Clinical trial results:
A Phase 2, Multicenter, Open-Label, Active Comparator-Controlled, Extension Trial to Evaluate the Long-Term Safety and Efficacy of CP-690,550 in Renal Allograft Recipients

Summary

EudraCT number	2008-002345-23
Trial protocol	DE ES PT BE NL IT CZ
Global end of trial date	09 June 2015

Results information

Result version number	v1 (current)
This version publication date	27 August 2016
First version publication date	27 August 2016

Trial information

Trial identification

Sponsor protocol code	A3921050

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00658359
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer, Inc.
Sponsor organisation address	Corporate Office: 235 East 42nd Street, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, 00-1 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center, Pfizer, 00-1 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	03 February 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	10 March 2015
Global end of trial reached?	Yes
Global end of trial date	09 June 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Participants who had completed 12 months treatment with tofacitinib or cyclosporine (CsA) in previous parent study (A3921030) continued study drugs for an additional 60 months in this extension study (except in Portugal where study treatment was continued through 3 years posttransplant, after which subjects completed a follow up visit 2 months after the last dose). The main objective of this trial was to evaluate the long-term safety, tolerability and efficacy of tofacitinib including the incidence of biopsy proven acute rejection (BPAR) (as interpreted by the central pathologist) and treated clinical acute rejection (episodes that were diagnosed clinically and received antirejection treatment).

Protection of trial subjects:

Throughout this study, subjects were monitored for clinical evidence of acute rejection, clinically significant infections, malignancies, and graft survival. In addition to the protocol biopsy scheduled at Month 36, allograft biopsy was considered when clinically indicated to assess the etiology of deteriorating renal function. A Data Monitoring Committee (DMC) was established for the study and acted in an advisory capacity to the sponsor’s study team. The DMC included internal (sponsor) members as well as members external to the sponsor who had transplant expertise. The DMC was responsible for ongoing monitoring of the efficacy and safety of subjects in the study according to the Charter. Any recommendations made by the DMC to alter the conduct of the study were forwarded to the sponsor for final decision. The sponsor forwarded such decisions to regulatory authorities, as appropriate.

Background therapy:

Participants also received oral mycophenolate mofetil (MMF) 1 to 2 gram tablet daily throughout this extension study (or up to 3 mg daily for Black participants). Prednisone 5mg daily (or equivalent) was also maintained through at least 12 months posttransplant (parent study).

Evidence for comparator:

Cyclosporine (CsA) was administered for up to 60 months as CsA microemulsion (Neoral® brand in the United States) orally twice daily (BID) in 2 equal doses approximately 12 hours apart. The dosage was adjusted to achieve a 12 hour trough whole blood level of approximately 75 to 200 nanograms per milliliter (ng/mL). The selection of the doses for this extension study was based on the review of data from the completed Study A3921030.

Actual start date of recruitment	18 August 2008
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	60 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 19
Country: Number of subjects enrolled	Belgium: 9
Country: Number of subjects enrolled	Brazil: 22

Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	Czech Republic: 2
Country: Number of subjects enrolled	France: 6
Country: Number of subjects enrolled	Germany: 4
Country: Number of subjects enrolled	Italy: 7
Country: Number of subjects enrolled	Korea, Republic of: 12
Country: Number of subjects enrolled	Netherlands: 5
Country: Number of subjects enrolled	Norway: 3
Country: Number of subjects enrolled	Poland: 4
Country: Number of subjects enrolled	Portugal: 7
Country: Number of subjects enrolled	Spain: 5
Country: Number of subjects enrolled	United States: 72
Worldwide total number of subjects	178
EEA total number of subjects	52

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	167
From 65 to 84 years	11
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited and studied between 18 August 2008 and 18 February 2015. Those with 6-month time-weighted concentrations at 2-hours postdose (TWC2) above the median (Amendment 3), negative/unknown Epstein-Barr virus (EBV) at transplant, cytomegalovirus disease or lymphocyte-depleting agents posttransplant (Amendment 4) were discontinued

Pre-assignment

Screening details:

Participants who had completed 12 months treatment with tofacitinib or cyclosporine (CsA) in previous parent study (A3921030) continued study drugs for an additional 60 months in this extension study.

Pre-assignment period milestones

Number of subjects started	178
Number of subjects completed	178

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Cyclosporine (CsA)

Arm description:

CsA was administered for up to 60 months as CsA microemulsion (Neoral® brand in the United States) orally twice daily (BID) in 2 equal doses approximately 12 hours apart. The dosage was adjusted to achieve a 12 hour trough whole blood level of approximately 75 to 200 nanograms per milliliter (ng/mL). Participants also received oral mycophenolate mofetil (MMF) 1 to 2 gram tablet daily throughout this extension study (or up to 3 mg daily for Black participants). Prednisone 5mg daily (or equivalent) was also maintained through at least 12 months posttransplant (parent study).

Arm type	Active comparator
Investigational medicinal product name	cyclosporine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral emulsion
Routes of administration	Oral use

Dosage and administration details:

Orally BID in 2 equal doses approximately 12 hours apart. The dosage was adjusted to achieve a 12 hour trough whole blood level of approximately 75 to 200 ng/mL

Arm title	Tofacitinib Less Intensive (LI)

Arm description:

Tofacitinib was administered for up to 60 months. During the parent study (A3921030), participants received 15 milligram (mg) tablet orally BID for Months 1 to 3 posttransplant then 10 mg tablet orally BID from Month 4. On entry to this extension study (Month 12), the dose was continued and tapered to 5 mg BID as early as Month 12 and by Month 18 posttransplant. Total tofacitinib LI treatment was up to 72 months posttransplant (12 months parent study and 60 months extension). Participants also received oral MMF 1 to 2 gram tablet daily throughout this extension study. Prednisone 5mg daily (or equivalent) was also maintained through at least 12 months posttransplant (parent study).

Arm type	Experimental

Investigational medicinal product name	tofacitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral 10mg BID on study entry reducing to 5mg BID by Month 18

Arm title	Tofacitinib More Intensive (MI)

Arm description:

Tofacitinib was administered for up to 60 months. During the parent study (A3921030), participants received 15 mg tablet orally BID for Months 1 to 6 posttransplant then 10 mg tablet orally BID from Month 7. On entry to this extension study (Month 12), the dose was continued and tapered to 5 mg BID as early as Month 12 and by Month 18 posttransplant. Total tofacitinib MI treatment was up to 72 months posttransplant (12 months parent study and 60 months extension). Participants also received oral MMF 1 to 2 gram tablet daily throughout this extension study. Prednisone 5mg daily (or equivalent) was also maintained through at least 12 months posttransplant (parent study).

Arm type	Experimental
Investigational medicinal product name	tofacitinib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oral 10mg BID on study entry reducing to 5mg BID by Month 18

Number of subjects in period 1	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)
Started	64	60	54
Completed	36	15	8
Not completed	28	45	46
Adverse event, serious fatal	3	1	2
Consent withdrawn by subject	7	4	2
Adverse event, non-fatal	13	6	9
Other reasons including protocol Amendment 3 and 4	2	31	29
Lost to follow-up	2	2	4
Protocol deviation	1	-	-
Lack of efficacy	-	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Cyclosporine (CsA)

Reporting group description:

CsA was administered for up to 60 months as CsA microemulsion (Neoral® brand in the United States) orally twice daily (BID) in 2 equal doses approximately 12 hours apart. The dosage was adjusted to achieve a 12 hour trough whole blood level of approximately 75 to 200 nanograms per milliliter (ng/mL). Participants also received oral mycophenolate mofetil (MMF) 1 to 2 gram tablet daily throughout this extension study (or up to 3 mg daily for Black participants). Prednisone 5mg daily (or equivalent) was also maintained through at least 12 months posttransplant (parent study).

Reporting group title	Tofacitinib Less Intensive (LI)

Reporting group description:

Tofacitinib was administered for up to 60 months. During the parent study (A3921030), participants received 15 milligram (mg) tablet orally BID for Months 1 to 3 posttransplant then 10 mg tablet orally BID from Month 4. On entry to this extension study (Month 12), the dose was continued and tapered to 5 mg BID as early as Month 12 and by Month 18 posttransplant. Total tofacitinib LI treatment was up to 72 months posttransplant (12 months parent study and 60 months extension). Participants also received oral MMF 1 to 2 gram tablet daily throughout this extension study. Prednisone 5mg daily (or equivalent) was also maintained through at least 12 months posttransplant (parent study).

Reporting group title	Tofacitinib More Intensive (MI)

Reporting group description:

Tofacitinib was administered for up to 60 months. During the parent study (A3921030), participants received 15 mg tablet orally BID for Months 1 to 6 posttransplant then 10 mg tablet orally BID from Month 7. On entry to this extension study (Month 12), the dose was continued and tapered to 5 mg BID as early as Month 12 and by Month 18 posttransplant. Total tofacitinib MI treatment was up to 72 months posttransplant (12 months parent study and 60 months extension). Participants also received oral MMF 1 to 2 gram tablet daily throughout this extension study. Prednisone 5mg daily (or equivalent) was also maintained through at least 12 months posttransplant (parent study).

Reporting group values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)
Number of subjects	64	60	54
Age categorical Units: Subjects			
Adults (18-64 years)	60	57	50
From 65-84 years	4	3	4
Age Continuous |			
Age refers to the beginning of the parent study (A3921030)			
Units: years			
arithmetic mean	46.4	45.7	48.5
standard deviation	± 12.7	± 12.6	± 10.9
Gender, Male/Female Units: Participants			
Female	20	19	14
Male	44	41	40
Race Units: Subjects			
White	46	45	34
Black	8	7	7
Asian	5	6	9
Other	5	2	4

Weight			
Weight refers to the beginning of the parent study (A3921030)			
Units: kilogram [kg]			
arithmetic mean	75.9	74.9	79.5
standard deviation	± 15.5	± 18.3	± 21.7
Body Mass Index			
Body mass index refers to the beginning of the parent study (A3921030)			
Units: kg/meter squared [kg/m^2]			
arithmetic mean	26.2	25.6	26.9
standard deviation	± 4.6	± 5	± 5.4
Height			
Height refers to the beginning of the parent study (A3921030)			
Units: centimeter [cm]			
arithmetic mean	169.8	170.5	171.1
standard deviation	± 9.3	± 9.9	± 11.3

Reporting group values	Total		
Number of subjects	178		
Age categorical Units: Subjects			
Adults (18-64 years)	167		
From 65-84 years	11		
Age Continuous |			
Age refers to the beginning of the parent study (A3921030)			
Units: years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female Units: Participants			
Female	53		
Male	125		
Race Units: Subjects			
White	125		
Black	22		
Asian	20		
Other	11		
Weight			
Weight refers to the beginning of the parent study (A3921030)			
Units: kilogram [kg]			
arithmetic mean			
standard deviation	-		
Body Mass Index			
Body mass index refers to the beginning of the parent study (A3921030)			
Units: kg/meter squared [kg/m^2]			
arithmetic mean			
standard deviation	-		
Height			
Height refers to the beginning of the parent study (A3921030)			
Units: centimeter [cm]			
arithmetic mean			

standard deviation	-		

Subject analysis sets	
Subject analysis set title	Full Analysis Set (FAS)
Subject analysis set type	Full analysis

Subject analysis set description:

The FAS included all subjects who were enrolled in the study and received at least 1 dose of study drug in Study A3921050.

Subject analysis set title	Safety Analysis Set
Subject analysis set type	Safety analysis

Subject analysis set description:

The Safety Analysis Set was defined as those subjects who received at least 1 dose of study drug in Study A3921050 (note that the FAS and the Safety Analysis Set were the same).

Reporting group values	Full Analysis Set (FAS)	Safety Analysis Set	
Number of subjects	178	178	
Age categorical Units: Subjects			
Adults (18-64 years)	167	167	
From 65-84 years	11	11	
Age Continuous |			
Age refers to the beginning of the parent study (A3921030)			
Units: years			
arithmetic mean	46.8	46.8	
standard deviation	± 12.2	± 12.2	
Gender, Male/Female Units: Participants			
Female	53	53	
Male	125	125	
Race Units: Subjects			
White	125	125	
Black	22	22	
Asian	20	20	
Other	11	11	
Weight			
Weight refers to the beginning of the parent study (A3921030)			
Units: kilogram [kg]			
arithmetic mean	76.7	76.7	
standard deviation	± 18.5	± 18.5	
Body Mass Index			
Body mass index refers to the beginning of the parent study (A3921030)			
Units: kg/meter squared [kg/m^2]			
arithmetic mean	26.2	26.2	
standard deviation	± 5	± 5	
Height			
Height refers to the beginning of the parent study (A3921030)			
Units: centimeter [cm]			

arithmetic mean standard deviation	170.4 ± 10.1	170.4 ± 10.1	

End points

End points reporting groups

Reporting group title	Cyclosporine (CsA)

Reporting group description:

CsA was administered for up to 60 months as CsA microemulsion (Neoral® brand in the United States) orally twice daily (BID) in 2 equal doses approximately 12 hours apart. The dosage was adjusted to achieve a 12 hour trough whole blood level of approximately 75 to 200 nanograms per milliliter (ng/mL). Participants also received oral mycophenolate mofetil (MMF) 1 to 2 gram tablet daily throughout this extension study (or up to 3 mg daily for Black participants). Prednisone 5mg daily (or equivalent) was also maintained through at least 12 months posttransplant (parent study).

Reporting group title	Tofacitinib Less Intensive (LI)

Reporting group description:

Tofacitinib was administered for up to 60 months. During the parent study (A3921030), participants received 15 milligram (mg) tablet orally BID for Months 1 to 3 posttransplant then 10 mg tablet orally BID from Month 4. On entry to this extension study (Month 12), the dose was continued and tapered to 5 mg BID as early as Month 12 and by Month 18 posttransplant. Total tofacitinib LI treatment was up to 72 months posttransplant (12 months parent study and 60 months extension). Participants also received oral MMF 1 to 2 gram tablet daily throughout this extension study. Prednisone 5mg daily (or equivalent) was also maintained through at least 12 months posttransplant (parent study).

Reporting group title	Tofacitinib More Intensive (MI)

Reporting group description:

Tofacitinib was administered for up to 60 months. During the parent study (A3921030), participants received 15 mg tablet orally BID for Months 1 to 6 posttransplant then 10 mg tablet orally BID from Month 7. On entry to this extension study (Month 12), the dose was continued and tapered to 5 mg BID as early as Month 12 and by Month 18 posttransplant. Total tofacitinib MI treatment was up to 72 months posttransplant (12 months parent study and 60 months extension). Participants also received oral MMF 1 to 2 gram tablet daily throughout this extension study. Prednisone 5mg daily (or equivalent) was also maintained through at least 12 months posttransplant (parent study).

Subject analysis set title	Full Analysis Set (FAS)
Subject analysis set type	Full analysis

Subject analysis set description:

The FAS included all subjects who were enrolled in the study and received at least 1 dose of study drug in Study A3921050.

Subject analysis set title	Safety Analysis Set
Subject analysis set type	Safety analysis

Subject analysis set description:

The Safety Analysis Set was defined as those subjects who received at least 1 dose of study drug in Study A3921050 (note that the FAS and the Safety Analysis Set were the same).

Primary: Kaplan-Meier Analysis of Percentage of Participants with Clinically Significant Infection (CSI) by Visit

End point title	Kaplan-Meier Analysis of Percentage of Participants with Clinically Significant Infection (CSI) by Visit

End point description:

CSI was defined as the presence of documented infection confirmed by culture, biopsy, genomic, or serologic findings post-randomization and requiring hospitalization or parenteral anti-infective treatment, or otherwise deemed significant by the investigator. The 'Number' and 'Confidence Interval 60%' columns represent cumulative proportions and 60% confidence intervals (CIs) as estimated from the fitted Kaplan-Meier curves for each treatment at scheduled visits.

End point type	Primary

End point timeframe:

Months 12, 15, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: Percentage of Participants				
number (confidence interval 60%)				
Month 12 (n=61, 55, 52)	4.69 (2.46 to 6.91)	8.33 (5.33 to 11.34)	3.7 (1.54 to 5.87)	
Month 15 (n=59,54,44)	7.81 (4.99 to 10.64)	10 (6.74 to 13.26)	18.52 (14.07 to 22.97)	
Month 18 (n=57,52,41)	9.4 (6.33 to 12.48)	13.33 (9.64 to 17.03)	20.46 (15.83 to 25.09)	
Month 24 (n=54,48,34)	11.02 (7.71 to 14.33)	18.33 (14.13 to 22.54)	24.49 (19.51 to 29.47)	
Month 30 (n=49,34,23)	12.8 (9.23 to 16.36)	25.42 (20.64 to 30.21)	29.46 (24 to 34.92)	
Month 36 (n=46,28,12)	14.62 (10.81 to 18.42)	27.83 (22.79 to 32.87)	34.89 (28.2 to 41.57)	
Month 42 (n=40,28,11)	14.62 (10.81 to 18.42)	27.83 (22.79 to 32.87)	34.89 (28.2 to 41.57)	
Month 48 (n=37,28,11)	16.81 (12.68 to 20.93)	27.83 (22.79 to 32.87)	34.89 (28.2 to 41.57)	
Month 54 (n=36,25,10)	19.05 (14.62 to 23.48)	33.08 (27.52 to 38.64)	34.89 (28.2 to 41.57)	
Month 60 (n=34,21,10)	19.05 (14.62 to 23.48)	36.13 (30.26 to 41.99)	34.89 (28.2 to 41.57)	
Month 66 (n=29,19,8)	19.05 (14.62 to 23.48)	36.13 (30.26 to 41.99)	34.89 (28.2 to 41.57)	
Month 72 (n=24,15,7)	21.94 (17.05 to 26.84)	40.12 (33.73 to 46.51)	43.03 (34.35 to 51.7)	

Statistical analyses

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description: Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[1]
P-value	= 0.6694
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	2.19
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-2.12
upper limit	6.5
Variability estimate	Standard error of the mean
Dispersion value	5.12

Notes:

[1] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description:	
Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[2]
P-value	= 0.0873
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	10.71
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	5.44
upper limit	15.98
Variability estimate	Standard error of the mean
Dispersion value	6.26

Notes:

[2] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	= 0.4912
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.93
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-0.87
upper limit	8.74
Variability estimate	Standard error of the mean
Dispersion value	5.71

Notes:

[3] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[4]
P-value	= 0.0942
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	11.06
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	5.5
upper limit	16.62
Variability estimate	Standard error of the mean
Dispersion value	6.61

Notes:

[4] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit

Statistical analysis description:

Month 24

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[5]
P-value	= 0.2499
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	7.31
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.96
upper limit	12.66
Variability estimate	Standard error of the mean
Dispersion value	6.36

Notes:

[5] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit

Statistical analysis description:

Month 24

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[6]
P-value	= 0.058
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	13.47

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	7.49
upper limit	19.45
Variability estimate	Standard error of the mean
Dispersion value	7.1

Notes:

[6] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[7]
P-value	= 0.075
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	12.62
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	6.66
upper limit	18.59
Variability estimate	Standard error of the mean
Dispersion value	7.09

Notes:

[7] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[8]
P-value	= 0.0316
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	16.66
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	10.14
upper limit	23.19
Variability estimate	Standard error of the mean
Dispersion value	7.75

Notes:

[8] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[9]
P-value	= 0.0783
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	13.21
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	6.9
upper limit	19.53
Variability estimate	Standard error of the mean
Dispersion value	7.5

Notes:

[9] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[10]
P-value	= 0.0266
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	20.27
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	12.58
upper limit	27.96
Variability estimate	Standard error of the mean
Dispersion value	9.14

Notes:

[10] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[11]
P-value	= 0.0783
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	13.21
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	6.9
upper limit	19.53
Variability estimate	Standard error of the mean
Dispersion value	7.5

Notes:

[11] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[12]
P-value	= 0.0266
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	20.27
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	12.58
upper limit	27.96
Variability estimate	Standard error of the mean
Dispersion value	9.14

Notes:

[12] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[13]
P-value	= 0.1545
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	11.02

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	4.51
upper limit	17.54
Variability estimate	Standard error of the mean
Dispersion value	7.74

Notes:

[13] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit

Statistical analysis description:

Month 48

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[14]
P-value	= 0.0528
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	18.08
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	10.22
upper limit	25.94
Variability estimate	Standard error of the mean
Dispersion value	9.34

Notes:

[14] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit

Statistical analysis description:

Month 54

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[15]
P-value	= 0.0968
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	14.03
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	6.92
upper limit	21.14
Variability estimate	Standard error of the mean
Dispersion value	8.45

Notes:

[15] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[16]
P-value	= 0.0966
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	15.83
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	7.81
upper limit	23.85
Variability estimate	Standard error of the mean
Dispersion value	9.53

Notes:

[16] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[17]
P-value	= 0.0507
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	17.07
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	9.72
upper limit	24.42
Variability estimate	Standard error of the mean
Dispersion value	8.74

Notes:

[17] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description:	
Month 60	

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[18]
P-value	= 0.0966
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	15.83
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	7.81
upper limit	23.85
Variability estimate	Standard error of the mean
Dispersion value	9.53

Notes:

[18] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit

Statistical analysis description:

Month 66

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[19]
P-value	= 0.0507
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	17.07
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	9.72
upper limit	24.42
Variability estimate	Standard error of the mean
Dispersion value	8.74

Notes:

[19] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit

Statistical analysis description:

Month 66

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[20]
P-value	= 0.0966
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	15.83
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	7.81
upper limit	23.85
Variability estimate	Standard error of the mean
Dispersion value	9.53

Notes:

[20] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[21]
P-value	= 0.0574
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	18.17
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	10.12
upper limit	26.22
Variability estimate	Standard error of the mean
Dispersion value	9.56

Notes:

[21] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[22]
P-value	= 0.0749
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	21.08

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	11.12
upper limit	31.04
Variability estimate	Standard error of the mean
Dispersion value	11.84

Notes:

[22] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description:	
Month 12	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[23]
P-value	= 0.4116
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.65
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-0.09
upper limit	7.38
Variability estimate	Standard error of the mean
Dispersion value	4.44

Notes:

[23] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with CSI by Visit
Statistical analysis description:	
Month 12	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[24]
P-value	= 0.7895
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-0.98
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-4.09
upper limit	2.12
Variability estimate	Standard error of the mean
Dispersion value	3.69

Notes:

[24] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Primary: Percentage of Participants with Malignancies

End point title	Percentage of Participants with Malignancies

End point description:

All treatment-emergent malignancies in Study A3921050 were included as collected on the Malignancy Case Report Form page.

End point type	Primary

End point timeframe:

Months 12 through 72.

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: Percentage of Participants				
number (not applicable)	10.9	13.3	14.8	

Statistical analyses

Statistical analysis title	Percentage of Participants with Malignancies
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[25]
P-value	= 0.683
Method	Chi-squared
Parameter estimate	Mean difference (final values)
Point estimate	2.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.1
upper limit	13.9
Variability estimate	Standard error of the mean
Dispersion value	5.9

Notes:

[25] - 'Mean difference' and 'standard error of the mean' refers to 'percentage difference' and 'standard error of the percentage difference'

Statistical analysis title	Percentage of Participants with Malignancies
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[26]
P-value	= 0.529
Method	Chi-squared
Parameter estimate	Mean difference (final values)
Point estimate	3.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.3
upper limit	16.1
Variability estimate	Standard error of the mean
Dispersion value	6.2

Notes:

[26] - 'Mean difference' and 'standard error of the mean' refers to 'percentage difference' and 'standard error of the percentage difference'

Primary: Least Squares Means of Measured Glomerular Filtration Rate (GFR) (Iohexol Serum Clearance in Milliliters per Minute [mL/min])

End point title	Least Squares Means of Measured Glomerular Filtration Rate (GFR) (Iohexol Serum Clearance in Milliliters per Minute [mL/min])

End point description:

GFR: an index of kidney function. GFR described the flow rate of filtered fluid through the kidney. GFR was calculated using iohexol serum clearance. For determination of iohexol serum clearance, iohexol was administered as an intravenous (IV) bolus over 5 minutes immediately after morning dosing of Tofacitinib or CsA on day of GFR evaluation. Blood samples for iohexol (3 millilitres [mL] each to provide a minimum of 1 mL serum) were collected into appropriately labeled tubes containing no additives at 120, 180, 240, and 300 minutes after the end of the iohexol IV bolus. A normal GFR is greater than (>) 90 mL/min, although children and older people usually have a lower GFR. Lower values indicated poor kidney function. A GFR less than (<) 15 mL/min indicated kidney failure.

End point type	Primary

End point timeframe:

Month 36

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	39	30	13	
Units: mL/min				
least squares mean (standard error)	67.63 (± 3.38)	76.86 (± 3.74)	75.86 (± 5.35)	

Statistical analyses

Statistical analysis title	Treatment Comparisons of Measured GFR
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority[27]
P-value	= 0.0699
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	9.23
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	4.97
upper limit	13.49
Variability estimate	Standard error of the mean
Dispersion value	5.04

Notes:

[27] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	Treatment Comparisons of Measured GFR
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	52
Analysis specification	Pre-specified
Analysis type	superiority[28]
P-value	= 0.1958
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	8.23
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	2.89
upper limit	13.58
Variability estimate	Standard error of the mean
Dispersion value	6.32

Notes:

[28] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Primary: Percentage of Participants with Progression of Chronic Allograft Lesions (CAL) at Month 36

End point title	Percentage of Participants with Progression of Chronic Allograft Lesions (CAL) at Month 36

End point description:

Progression of CAL was defined as an increase in the Banff chronicity score (Banff-CS) in biopsy from the implantation (baseline) biopsy in a given participant. Banff-CS was the sum of the Banff scores for the 4 chronic basic lesions (allograft glomerulopathy [cg] + interstitial fibrosis [ci] + tubular atrophy [ct] + vascular intimal thickening [cv]). The Banff-CS ranged from 0-12, higher score indicated greater lesions and Month 36 Banff-CS greater than the implantation biopsy score indicated progression of lesions.

End point type	Primary

End point timeframe:

Month 36

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	18	8	
Units: Percentage of Participants				
number (not applicable)	87.5	77.78	87.5	

Statistical analyses

Statistical analysis title	Percentage of Participants with Progression of CAL
Statistical analysis description: Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority[29]
P-value	= 0.438
Method	Chi-squared
Parameter estimate	Difference in percentage
Point estimate	-9.72
Confidence interval	
level	Other: 0 %
sides	2-sided
lower limit	-100
upper limit	100
Variability estimate	Standard deviation
Dispersion value	0

Notes:

[29] - Analysis uses Tofacitinib LI minus CsA. No confidence interval or dispersion value was calculated. The confidence interval and dispersion values provided are artificial numbers NOT from the study.

Statistical analysis title	Percentage of Participants with Progressive CAL
Statistical analysis description: Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority[30]
P-value	> 0.999
Method	Chi-squared
Parameter estimate	Difference in percentage
Point estimate	0

Confidence interval	
level	Other: 0 %
sides	2-sided
lower limit	-100
upper limit	100
Variability estimate	Standard deviation
Dispersion value	0

Notes:

[30] - Analysis uses Tofacitinib MI minus CsA. No confidence interval or dispersion value was calculated. The confidence interval and dispersion values provided are artificial numbers NOT from the study

Primary: Kaplan-Meier Analysis of Percentage of Participants with first Biopsy Proven Acute Rejection (BPAR) by Visit

End point title	Kaplan-Meier Analysis of Percentage of Participants with first Biopsy Proven Acute Rejection (BPAR) by Visit

End point description:

BPAR was category acute rejection as interpreted by the central blinded pathologist according to the Banff 97 working classification. The 'Number' and 'Confidence Interval 60%' columns represent cumulative proportions and 60% CIs as estimated from the fitted Kaplan-Meier curves for each treatment at scheduled visits..

End point type	Primary

End point timeframe:

Months 12, 15, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: Percentage of Participants				
number (confidence interval 60%)				
Month 12 (n=60,54,51)	6.25 (3.7 to 8.8)	10 (6.74 to 13.26)	5.56 (2.93 to 8.18)	
Month 15 (n=59,54,50)	7.81 (4.99 to 10.64)	10 (6.74 to 13.26)	7.41 (4.41 to 10.41)	
Month 18 (n=57,54,48)	9.4 (6.33 to 12.48)	10 (6.74 to 13.26)	7.41 (4.41 to 10.41)	
Month 24 (n=55,53,42)	9.4 (6.33 to 12.48)	10 (6.74 to 13.26)	7.41 (4.41 to 10.41)	
Month 30 (n=51,37,28)	9.4 (6.33 to 12.48)	10 (6.74 to 13.26)	7.41 (4.41 to 10.41)	
Month 36 (n=48,28,14)	11.18 (7.82 to 14.54)	10 (6.74 to 13.26)	7.41 (4.41 to 10.41)	
Month 42 (n=40,28,13)	13.34 (9.61 to 17.08)	10 (6.74 to 13.26)	7.41 (4.41 to 10.41)	
Month 48 (n=38,28,13)	13.34 (9.61 to 17.08)	10 (6.74 to 13.26)	7.41 (4.41 to 10.41)	
Month 54 (n=38,27,12)	13.34 (9.61 to 17.08)	10 (6.74 to 13.26)	7.41 (4.41 to 10.41)	
Month 60 (n=36,23,11)	13.34 (9.61 to 17.08)	10 (6.74 to 13.26)	7.41 (4.41 to 10.41)	
Month 66 (n=31,20,10)	13.34 (9.61 to 17.08)	10 (6.74 to 13.26)	7.41 (4.41 to 10.41)	
Month 72 (n=28,18,10)	13.34 (9.61 to 17.08)	10 (6.74 to 13.26)	7.41 (4.41 to 10.41)	

Statistical analyses

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[31]
P-value	= 0.6694
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	2.19
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-2.12
upper limit	6.5
Variability estimate	Standard error of the mean
Dispersion value	5.12

Notes:

[31] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[32]
P-value	= 0.934
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-0.41
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-4.52
upper limit	3.71
Variability estimate	Standard error of the mean
Dispersion value	4.89

Notes:

[32] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[33]
P-value	= 0.9106
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	0.6
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-3.88
upper limit	5.08
Variability estimate	Standard error of the mean
Dispersion value	5.32

Notes:

[33] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[34]
P-value	= 0.696
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-1.99
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-6.29
upper limit	2.3
Variability estimate	Standard error of the mean
Dispersion value	5.1

Notes:

[34] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[35]
P-value	= 0.9106
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	0.6
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-3.88
upper limit	5.08
Variability estimate	Standard error of the mean
Dispersion value	5.32

Notes:

[35] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[36]
P-value	= 0.696
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-1.99
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-6.29
upper limit	2.3
Variability estimate	Standard error of the mean
Dispersion value	5.1

Notes:

[36] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[37]
P-value	= 0.9106
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	0.6

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-3.88
upper limit	5.08
Variability estimate	Standard error of the mean
Dispersion value	5.32

Notes:

[37] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[38]
P-value	= 0.696
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-1.99
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-6.29
upper limit	2.3
Variability estimate	Standard error of the mean
Dispersion value	5.1

Notes:

[38] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[39]
P-value	= 0.8322
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-1.18
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-5.86
upper limit	3.5
Variability estimate	Standard error of the mean
Dispersion value	5.56

Notes:

[39] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[40]
P-value	= 0.4809
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-3.77
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-8.27
upper limit	0.73
Variability estimate	Standard error of the mean
Dispersion value	5.35

Notes:

[40] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[41]
P-value	= 0.5704
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-3.34
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-8.31
upper limit	1.62
Variability estimate	Standard error of the mean
Dispersion value	5.89

Notes:

[41] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 42	

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[42]
P-value	= 0.2972
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-5.94
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-10.73
upper limit	-1.14
Variability estimate	Standard error of the mean
Dispersion value	5.7

Notes:

[42] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR

Statistical analysis description:

Month 48

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[43]
P-value	= 0.5704
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-3.34
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-8.31
upper limit	1.62
Variability estimate	Standard error of the mean
Dispersion value	5.89

Notes:

[43] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR

Statistical analysis description:

Month 48

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[44]
P-value	= 0.2972
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-5.94
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-10.73
upper limit	-1.14
Variability estimate	Standard error of the mean
Dispersion value	5.7

Notes:

[44] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[45]
P-value	= 0.5704
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-3.34
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-8.31
upper limit	1.62
Variability estimate	Standard error of the mean
Dispersion value	5.89

Notes:

[45] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[46]
P-value	= 0.2972
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-5.94

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-10.73
upper limit	-1.14
Variability estimate	Standard error of the mean
Dispersion value	5.7

Notes:

[46] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[47]
P-value	= 0.5704
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-3.34
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-8.31
upper limit	1.62
Variability estimate	Standard error of the mean
Dispersion value	5.89

Notes:

[47] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[48]
P-value	= 0.2972
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-5.94
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-10.73
upper limit	-1.14
Variability estimate	Standard error of the mean
Dispersion value	5.7

Notes:

[48] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[49]
P-value	= 0.5704
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-3.34
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-8.31
upper limit	1.62
Variability estimate	Standard error of the mean
Dispersion value	5.89

Notes:

[49] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[50]
P-value	= 0.2972
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-5.94
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-10.73
upper limit	-1.14
Variability estimate	Standard error of the mean
Dispersion value	5.7

Notes:

[50] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR
Statistical analysis description:	
Month 72	

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[51]
P-value	= 0.5704
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-3.34
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-8.31
upper limit	1.62
Variability estimate	Standard error of the mean
Dispersion value	5.89

Notes:

[51] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR

Statistical analysis description:

Month 72

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[52]
P-value	= 0.2972
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-5.94
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-10.73
upper limit	-1.14
Variability estimate	Standard error of the mean
Dispersion value	5.7

Notes:

[52] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR

Statistical analysis description:

Month 12

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[53]
P-value	= 0.4455
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.75
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-0.39
upper limit	7.89
Variability estimate	Standard error of the mean
Dispersion value	4.91

Notes:

[53] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with First BPAR

Statistical analysis description:

Month 12

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[54]
P-value	= 0.873
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-0.69
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-4.35
upper limit	2.96
Variability estimate	Standard error of the mean
Dispersion value	4.34

Notes:

[54] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Primary: Kaplan-Meier Analysis of Percentage of Participants with Treated Clinical Acute Rejection (TCAR) by Visit

End point title	Kaplan-Meier Analysis of Percentage of Participants with Treated Clinical Acute Rejection (TCAR) by Visit

End point description:

Treated clinical acute rejection (TCAR) was defined as an acute rejection episode that was diagnosed based on local biopsy readout and received anti-rejection treatment. The 'Number' and 'Confidence Interval 60%' columns represent cumulative proportions and 60% CIs as estimated from the fitted Kaplan-Meier curves for each treatment at scheduled visits..

End point type	Primary

End point timeframe:

Months 12, 15, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: Percentage of Participants				
number (confidence interval 60%)				
Month 12 (n=55,56,49)	14.06 (10.41 to 17.72)	6.67 (3.96 to 9.38)	9.26 (5.94 to 12.58)	
Month 15 (n=53,56,48)	17.19 (13.22 to 21.16)	6.67 (3.96 to 9.38)	11.11 (7.51 to 14.71)	
Month 18 (n=51,54,46)	18.75 (14.64 to 22.86)	10 (6.74 to 13.26)	11.11 (7.51 to 14.71)	
Month 24 (n=49,52,40)	18.75 (14.64 to 22.86)	11.67 (8.18 to 15.15)	11.11 (7.51 to 14.71)	
Month 30 (n=46,37,27)	20.48 (16.21 to 24.75)	11.67 (8.18 to 15.15)	11.11 (7.51 to 14.71)	
Month 36 (n=42,29,14)	23.94 (19.38 to 28.49)	11.67 (8.18 to 15.15)	11.11 (7.51 to 14.71)	
Month 42 (n=36,29,13)	27.56 (22.74 to 32.38)	11.67 (8.18 to 15.15)	11.11 (7.51 to 14.71)	
Month 48 (n=34,29,13)	27.56 (22.74 to 32.38)	11.67 (8.18 to 15.15)	11.11 (7.51 to 14.71)	
Month 54 (n=33,28,12)	29.69 (24.69 to 34.69)	11.67 (8.18 to 15.15)	11.11 (7.51 to 14.71)	
Month 60 (n=30,24,11)	29.69 (24.69 to 34.69)	11.67 (8.18 to 15.15)	11.11 (7.51 to 14.71)	
Month 66 (n=25,21,9)	29.69 (24.69 to 34.69)	11.67 (8.18 to 15.15)	11.11 (7.51 to 14.71)	
Month 72 (n=22,18,9)	29.69 (24.69 to 34.69)	11.67 (8.18 to 15.15)	11.11 (7.51 to 14.71)	

Statistical analyses

Statistical analysis title	Percentage of Participants with TCAR by Visit
Statistical analysis description: Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[55]
P-value	= 0.0654
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-10.52
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-15.33
upper limit	-5.71

Variability estimate	Standard error of the mean
Dispersion value	5.71

Notes:

[55] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit

Statistical analysis description:

Month 15

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[56]
P-value	= 0.3398
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-6.08
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-11.43
upper limit	-0.72
Variability estimate	Standard error of the mean
Dispersion value	6.37

Notes:

[56] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit

Statistical analysis description:

Month 18

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[57]
P-value	= 0.1601
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-8.75
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-13.99
upper limit	-3.51
Variability estimate	Standard error of the mean
Dispersion value	6.23

Notes:

[57] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit

Statistical analysis description:

Month 18

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[58]
P-value	= 0.239
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-7.64
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-13.1
upper limit	-2.18
Variability estimate	Standard error of the mean
Dispersion value	6.49

Notes:

[58] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit

Statistical analysis description:

Month 24

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[59]
P-value	= 0.2685
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-7.08
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-12.47
upper limit	-1.7
Variability estimate	Standard error of the mean
Dispersion value	6.4

Notes:

[59] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit

Statistical analysis description:

Month 24

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[60]
P-value	= 0.239
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-7.64
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-13.1
upper limit	-2.18
Variability estimate	Standard error of the mean
Dispersion value	6.49

Notes:

[60] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[61]
P-value	= 0.1785
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-8.81
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-14.32
upper limit	-3.3
Variability estimate	Standard error of the mean
Dispersion value	6.55

Notes:

[61] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[62]
P-value	= 0.158
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-9.37

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-14.95
upper limit	-3.78
Variability estimate	Standard error of the mean
Dispersion value	6.63

Notes:

[62] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit

Statistical analysis description:

Month 36

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[63]
P-value	= 0.0718
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-12.27
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-18
upper limit	-6.53
Variability estimate	Standard error of the mean
Dispersion value	6.81

Notes:

[63] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit

Statistical analysis description:

Month 36

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[64]
P-value	= 0.0629
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-12.83
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-18.63
upper limit	-7.02
Variability estimate	Standard error of the mean
Dispersion value	6.9

Notes:

[64] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[65]
P-value	= 0.0246
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-15.89
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-21.84
upper limit	-9.94
Variability estimate	Standard error of the mean
Dispersion value	7.07

Notes:

[65] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[66]
P-value	= 0.0214
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-16.45
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-22.46
upper limit	-10.43
Variability estimate	Standard error of the mean
Dispersion value	7.15

Notes:

[66] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit
Statistical analysis description:	
Month 48	

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[67]
P-value	= 0.0246
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-15.89
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-21.84
upper limit	-9.94
Variability estimate	Standard error of the mean
Dispersion value	7.07

Notes:

[67] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit

Statistical analysis description:

Month 48

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[68]
P-value	= 0.0214
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-16.45
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-22.46
upper limit	-10.43
Variability estimate	Standard error of the mean
Dispersion value	7.15

Notes:

[68] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit

Statistical analysis description:

Month 54

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[69]
P-value	= 0.0128
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-18.02
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-24.12
upper limit	-11.93
Variability estimate	Standard error of the mean
Dispersion value	7.24

Notes:

[69] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[70]
P-value	= 0.0111
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-18.58
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-24.74
upper limit	-12.42
Variability estimate	Standard error of the mean
Dispersion value	7.32

Notes:

[70] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[71]
P-value	= 0.0128
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-18.02

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-24.12
upper limit	-11.93
Variability estimate	Standard error of the mean
Dispersion value	7.24

Notes:

[71] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit

Statistical analysis description:

Month 60

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[72]
P-value	= 0.0111
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-18.58
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-24.74
upper limit	-12.42
Variability estimate	Standard error of the mean
Dispersion value	7.32

Notes:

[72] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit

Statistical analysis description:

Month 66

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[73]
P-value	= 0.0128
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-18.02
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-24.12
upper limit	-11.93
Variability estimate	Standard error of the mean
Dispersion value	7.24

Notes:

[73] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[74]
P-value	= 0.0111
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-18.58
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-24.74
upper limit	-12.42
Variability estimate	Standard error of the mean
Dispersion value	7.32

Notes:

[74] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[75]
P-value	= 0.0128
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-18.02
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-24.12
upper limit	-11.93
Variability estimate	Standard error of the mean
Dispersion value	7.24

Notes:

[75] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit
Statistical analysis description:	
Month 72	

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[76]
P-value	= 0.0111
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-18.58
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-24.74
upper limit	-12.42
Variability estimate	Standard error of the mean
Dispersion value	7.32

Notes:

[76] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit

Statistical analysis description:

Month 12

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[77]
P-value	= 0.1715
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-7.4
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-11.95
upper limit	-2.84
Variability estimate	Standard error of the mean
Dispersion value	5.41

Notes:

[77] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with TCAR by Visit

Statistical analysis description:

Month 12

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[78]
P-value	= 0.4131
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-4.8
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-9.74
upper limit	0.14
Variability estimate	Standard error of the mean
Dispersion value	5.87

Notes:

[78] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Secondary: Kaplan-Meier Analysis of Percentage of Participants with Efficacy Failure by Visit

End point title	Kaplan-Meier Analysis of Percentage of Participants with Efficacy Failure by Visit

End point description:

Efficacy failure was the first occurrence of BPAR diagnosed by the central pathologist or graft loss including participant death. BPAR (category acute rejection) was interpreted by the central blinded pathologist according to the Banff 97 working classification. The 'Number' and 'Confidence Interval 60%' columns represent cumulative proportions and 60% CIs as estimated from the fitted Kaplan-Meier curves for each treatment at scheduled visits.

End point type	Secondary

End point timeframe:

Months 12, 15, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: Percentage of Participants				
number (confidence interval 60%)				
Month 12 (n=60,54,51)	6.25 (3.7 to 8.8)	10 (6.74 to 13.26)	5.56 (2.93 to 8.18)	
Month 15 (n=58,54,49)	7.81 (4.99 to 10.64)	10 (6.74 to 13.26)	9.26 (5.94 to 12.58)	
Month 18 (n=56,54,49)	10.99 (7.69 to 14.29)	10 (6.74 to 13.26)	9.26 (5.94 to 12.58)	
Month 24 (n=54,54,46)	10.99 (7.69 to 14.29)	10 (6.74 to 13.26)	14.81 (10.75 to 18.88)	
Month 30 (n=53,52,46)	12.64 (9.12 to 16.16)	10 (6.74 to 13.26)	14.81 (10.75 to 18.88)	
Month 36 (n=51,48,42)	15.94 (12.04 to 19.83)	15.19 (11.26 to 19.12)	16.71 (12.43 to 20.99)	
Month 42 (n=44,47,41)	19.59 (15.3 to 23.88)	15.19 (11.26 to 19.12)	18.69 (14.2 to 23.18)	

Month 48 (n=43,44,38)	21.42 (16.96 to 25.88)	18.84 (14.52 to 23.16)	18.69 (14.2 to 23.18)	
Month 54 (n=41,44,36)	23.25 (18.63 to 27.86)	18.84 (14.52 to 23.16)	18.69 (14.2 to 23.18)	
Month 60 (n=41,44,35)	23.25 (18.63 to 27.86)	18.84 (14.52 to 23.16)	20.95 (16.2 to 25.7)	
Month 66 (n=39,42,29)	23.25 (18.63 to 27.86)	18.84 (14.52 to 23.16)	20.95 (16.2 to 25.7)	
Month 72 (n=35,28,19)	23.25 (18.63 to 27.86)	22.81 (18.1 to 27.51)	20.95 (16.2 to 25.7)	

Statistical analyses

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[79]
P-value	= 0.6694
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	2.19
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-2.12
upper limit	6.5
Variability estimate	Standard error of the mean
Dispersion value	5.12

Notes:

[79] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[80]
P-value	= 0.7799
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	1.45
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-2.91
upper limit	5.8

Variability estimate	Standard error of the mean
Dispersion value	5.18

Notes:

[80] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure

Statistical analysis description:

Month 18

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[81]
P-value	= 0.8572
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-0.99
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-5.63
upper limit	3.65
Variability estimate	Standard error of the mean
Dispersion value	5.51

Notes:

[81] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure

Statistical analysis description:

Month 18

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[82]
P-value	= 0.7555
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-1.73
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-6.41
upper limit	2.95
Variability estimate	Standard error of the mean
Dispersion value	5.56

Notes:

[82] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure

Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[83]
P-value	= 0.8572
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-0.99
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-5.63
upper limit	3.65
Variability estimate	Standard error of the mean
Dispersion value	5.51

Notes:

[83] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[84]
P-value	= 0.539
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.82
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-1.41
upper limit	9.06
Variability estimate	Standard error of the mean
Dispersion value	6.22

Notes:

[84] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[85]
P-value	= 0.6432
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-2.64
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-7.44
upper limit	2.16
Variability estimate	Standard error of the mean
Dispersion value	5.7

Notes:

[85] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[86]
P-value	= 0.7336
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	2.18
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-3.2
upper limit	7.55
Variability estimate	Standard error of the mean
Dispersion value	6.39

Notes:

[86] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[87]
P-value	= 0.9099
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-0.74

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-6.28
upper limit	4.79
Variability estimate	Standard error of the mean
Dispersion value	6.57

Notes:

[87] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[88]
P-value	= 0.9106
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	0.77
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-5.01
upper limit	6.56
Variability estimate	Standard error of the mean
Dispersion value	6.87

Notes:

[88] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[89]
P-value	= 0.5244
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-4.4
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-10.22
upper limit	1.42
Variability estimate	Standard error of the mean
Dispersion value	6.91

Notes:

[89] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[90]
P-value	= 0.9029
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-0.9
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-7.11
upper limit	5.31
Variability estimate	Standard error of the mean
Dispersion value	7.38

Notes:

[90] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[91]
P-value	= 0.7267
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-2.58
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-8.78
upper limit	3.63
Variability estimate	Standard error of the mean
Dispersion value	7.38

Notes:

[91] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 48	

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[92]
P-value	= 0.7168
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-2.73
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-9.06
upper limit	3.6
Variability estimate	Standard error of the mean
Dispersion value	7.52

Notes:

[92] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure

Statistical analysis description:

Month 54

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[93]
P-value	= 0.5574
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-4.4
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-10.72
upper limit	1.91
Variability estimate	Standard error of the mean
Dispersion value	7.51

Notes:

[93] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure

Statistical analysis description:

Month 54

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[94]
P-value	= 0.5515
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-4.56
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-10.99
upper limit	1.88
Variability estimate	Standard error of the mean
Dispersion value	7.65

Notes:

[94] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[95]
P-value	= 0.5574
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-4.4
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-10.72
upper limit	1.91
Variability estimate	Standard error of the mean
Dispersion value	7.51

Notes:

[95] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[96]
P-value	= 0.7704
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-2.3

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-8.92
upper limit	4.33
Variability estimate	Standard error of the mean
Dispersion value	7.87

Notes:

[96] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[97]
P-value	= 0.5574
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-4.4
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-10.72
upper limit	1.91
Variability estimate	Standard error of the mean
Dispersion value	7.51

Notes:

[97] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[98]
P-value	= 0.7704
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-2.3
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-8.92
upper limit	4.33
Variability estimate	Standard error of the mean
Dispersion value	7.87

Notes:

[98] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[99]
P-value	= 0.9551
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-0.44
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-7.03
upper limit	6.15
Variability estimate	Standard error of the mean
Dispersion value	7.83

Notes:

[99] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[100]
P-value	= 0.7704
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-2.3
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-8.92
upper limit	4.33
Variability estimate	Standard error of the mean
Dispersion value	7.87

Notes:

[100] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure
Statistical analysis description:	
Month 12	

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[101]
P-value	= 0.4455
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.75
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-0.39
upper limit	7.89
Variability estimate	Standard error of the mean
Dispersion value	4.91

Notes:

[101] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Efficacy Failure

Statistical analysis description:

Month 12

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[102]
P-value	= 0.873
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-0.69
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-4.35
upper limit	2.96
Variability estimate	Standard error of the mean
Dispersion value	4.34

Notes:

[102] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Secondary: Kaplan-Meier Analysis of Percentage of Participants with Combined Banff Rejection (BR) by Visit

End point title	Kaplan-Meier Analysis of Percentage of Participants with Combined Banff Rejection (BR) by Visit

End point description:

Banff 97: standard classification for scoring and classifying rejection of kidney transplant biopsies in 6 diagnostic categories: normal, antibody-mediated rejection, borderline changes: 'suspicious' for acute cellular rejection, acute/active cellular rejection, chronic/sclerosing allograft nephropathy, and other. Combined Banff rejection calculated from categories of antibody-mediated rejection (Category 2) plus borderline changes (Category 3) plus acute rejection (Category 4), as interpreted by the central pathologist. The 'Number' and 'Confidence Interval 60%' columns represent cumulative proportions and 60% CIs as estimated from the fitted Kaplan-Meier curves for each treatment at scheduled visits.

End point type	Secondary
End point timeframe: Months 12, 15, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72	

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: Percentage of Participants				
number (confidence interval 60%)				
Month 12 (n=54,52,48)	15.63 (11.81 to 19.44)	13.33 (9.64 to 17.03)	11.11 (7.51 to 14.71)	
Month 15 (n=51,52,45)	20.31 (16.08 to 24.55)	13.33 (9.64 to 17.03)	16.67 (12.4 to 20.93)	
Month 18 (n=49,52,43)	21.91 (17.55 to 26.26)	13.33 (9.64 to 17.03)	16.67 (12.4 to 20.93)	
Month 24 (n=46,50,37)	23.57 (19.09 to 28.05)	15 (11.12 to 18.88)	18.6 (14.13 to 23.07)	
Month 30 (n=44,37,23)	23.57 (19.09 to 28.05)	15 (11.12 to 18.88)	21.41 (16.51 to 26.31)	
Month 36 (n=41,28,12)	25.3 (20.69 to 29.92)	15 (11.12 to 18.88)	21.41 (16.51 to 26.31)	
Month 42 (n=34,28,11)	27.44 (22.62 to 32.26)	15 (11.12 to 18.88)	21.41 (16.51 to 26.31)	
Month 48 (n=33,28,11)	27.44 (22.62 to 32.26)	15 (11.12 to 18.88)	21.41 (16.51 to 26.31)	
Month 54 (n=33,27,10)	27.44 (22.62 to 32.26)	15 (11.12 to 18.88)	21.41 (16.51 to 26.31)	
Month 60 (n=31,23,9)	27.44 (22.62 to 32.26)	15 (11.12 to 18.88)	21.41 (16.51 to 26.31)	
Month 66 (n=26,20,9)	27.44 (22.62 to 32.26)	15 (11.12 to 18.88)	21.41 (16.51 to 26.31)	
Month 72 (n=24,18,9)	27.44 (22.62 to 32.26)	15 (11.12 to 18.88)	21.41 (16.51 to 26.31)	

Statistical analyses

Statistical analysis title	Percentage of Participants with Combined BR
Statistical analysis description: Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[103]
P-value	= 0.2957
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-6.98

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-12.6
upper limit	-1.36
Variability estimate	Standard error of the mean
Dispersion value	6.67

Notes:

[103] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR

Statistical analysis description:

Month 15

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[104]
P-value	= 0.6097
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-3.65
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-9.66
upper limit	2.37
Variability estimate	Standard error of the mean
Dispersion value	7.14

Notes:

[104] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR

Statistical analysis description:

Month 18

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[105]
P-value	= 0.2064
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-8.57
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-14.28
upper limit	-2.86
Variability estimate	Standard error of the mean
Dispersion value	6.79

Notes:

[105] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[106]
P-value	= 0.4696
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-5.24
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-11.34
upper limit	0.86
Variability estimate	Standard error of the mean
Dispersion value	7.25

Notes:

[106] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[107]
P-value	= 0.2238
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-8.57
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-14.5
upper limit	-2.64
Variability estimate	Standard error of the mean
Dispersion value	7.04

Notes:

[107] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR
Statistical analysis description:	
Month 24	

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[108]
P-value	= 0.5093
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-4.96
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-11.29
upper limit	1.37
Variability estimate	Standard error of the mean
Dispersion value	7.52

Notes:

[108] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR

Statistical analysis description:

Month 30

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[109]
P-value	= 0.2238
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-8.57
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-14.5
upper limit	-2.64
Variability estimate	Standard error of the mean
Dispersion value	7.04

Notes:

[109] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR

Statistical analysis description:

Month 30

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[110]
P-value	= 0.7846
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-2.16
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-8.8
upper limit	4.48
Variability estimate	Standard error of the mean
Dispersion value	7.89

Notes:

[110] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR

Statistical analysis description:

Month 36

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[111]
P-value	= 0.1501
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-10.3
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-16.33
upper limit	-4.28
Variability estimate	Standard error of the mean
Dispersion value	7.16

Notes:

[111] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR

Statistical analysis description:

Month 36

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[112]
P-value	= 0.6263
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-3.89

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-10.62
upper limit	2.84
Variability estimate	Standard error of the mean
Dispersion value	8

Notes:

[112] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[113]
P-value	= 0.0905
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-12.44
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-18.62
upper limit	-6.25
Variability estimate	Standard error of the mean
Dispersion value	7.35

Notes:

[113] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[114]
P-value	= 0.4604
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-6.03
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-12.9
upper limit	0.84
Variability estimate	Standard error of the mean
Dispersion value	8.16

Notes:

[114] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[115]
P-value	= 0.0905
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-12.44
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-18.62
upper limit	-6.25
Variability estimate	Standard error of the mean
Dispersion value	7.35

Notes:

[115] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[116]
P-value	= 0.4604
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-6.03
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-12.9
upper limit	0.84
Variability estimate	Standard error of the mean
Dispersion value	8.16

Notes:

[116] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR
Statistical analysis description:	
Month 54	

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[117]
P-value	= 0.0905
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-12.44
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-18.62
upper limit	-6.25
Variability estimate	Standard error of the mean
Dispersion value	7.35

Notes:

[117] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR

Statistical analysis description:

Month 54

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[118]
P-value	= 0.4604
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-6.03
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-12.9
upper limit	0.84
Variability estimate	Standard error of the mean
Dispersion value	8.16

Notes:

[118] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR

Statistical analysis description:

Month 60

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[119]
P-value	= 0.0905
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-12.44
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-18.62
upper limit	-6.25
Variability estimate	Standard error of the mean
Dispersion value	7.35

Notes:

[119] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR

Statistical analysis description:

Month 60

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[120]
P-value	= 0.4604
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-6.03
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-12.9
upper limit	0.84
Variability estimate	Standard error of the mean
Dispersion value	8.16

Notes:

[120] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR

Statistical analysis description:

Month 66

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[121]
P-value	= 0.0905
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-12.44

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-18.62
upper limit	-6.25
Variability estimate	Standard error of the mean
Dispersion value	7.35

Notes:

[121] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR

Statistical analysis description:

Month 66

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[122]
P-value	= 0.4604
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-6.03
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-12.9
upper limit	0.84
Variability estimate	Standard error of the mean
Dispersion value	8.16

Notes:

[122] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR

Statistical analysis description:

Month 72

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[123]
P-value	= 0.0905
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-12.44
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-18.62
upper limit	-6.25
Variability estimate	Standard error of the mean
Dispersion value	7.35

Notes:

[123] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[124]
P-value	= 0.4604
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-6.03
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-12.9
upper limit	0.84
Variability estimate	Standard error of the mean
Dispersion value	8.16

Notes:

[124] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR
Statistical analysis description:	
Month 12	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[125]
P-value	= 0.7166
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-2.29
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-7.61
upper limit	3.02
Variability estimate	Standard error of the mean
Dispersion value	6.31

Notes:

[125] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants with Combined BR
Statistical analysis description:	
Month 12	

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[126]
P-value	= 0.4692
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-4.51
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-9.76
upper limit	0.73
Variability estimate	Standard error of the mean
Dispersion value	6.24

Notes:

[126] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Secondary: Kaplan-Meier Analysis of Percent of Participants with Graft Survival with Death Censored by Visit

End point title	Kaplan-Meier Analysis of Percent of Participants with Graft Survival with Death Censored by Visit

End point description:

Graft loss was defined as graft nephrectomy, subject death, retransplantation, or return to dialysis for at least 6 consecutive weeks. The 'Number' and 'Confidence Interval 60%' columns represent cumulative proportions and 60% CIs as estimated from the fitted Kaplan-Meier curves for each treatment at scheduled visits. Included data up to 2 months postdose in the clinical Follow-up visit.

End point type	Secondary

End point timeframe:

Months 12, 15, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: Percentage of participants				
number (confidence interval 60%)				
Month 12 (n=64,60,54)	100 (99.58 to 100)	100 (98.48 to 100)	100 (98.32 to 100)	
Month 15 (n=64,60,54)	100 (95.58 to 100)	100 (98.48 to 100)	100 (98.32 to 100)	
Month 18 (n=62,59,51)	100 (98.53 to 100)	100 (98.46 to 100)	100 (98.22 to 100)	
Month 24 (n=59,58,45)	100 (98.46 to 100)	100 (98.43 to 100)	100 (97.98 to 100)	
Month 30 (n=55,42,31)	98.31 (96.89 to 99.72)	100 (97.84 to 100)	100 (97.09 to 100)	
Month 36 (n=53,32,16)	96.48 (94.43 to 98.54)	100 (97.18 to 100)	100 (94.43 to 100)	
Month 42 (n=46,32,15)	96.48 (94.43 to 98.54)	100 (97.18 to 100)	100 (94.07 to 100)	

Month 48 (n=44,32,15)	96.48 (94.43 to 98.54)	100 (97.18 to 100)	100 (94.07 to 100)	
Month 54 (n=43,31,14)	96.48 (94.43 to 98.54)	100 (97.09 to 100)	100 (93.66 to 100)	
Month 60 (n=40,26,13)	96.48 (94.43 to 98.54)	100 (96.54 to 100)	100 (93.19 to 100)	
Month 66 (n=35,23,11)	96.48 (94.43 to 98.54)	100 (96.09 to 100)	100 (92.01 to 100)	
Month 72 (n=31,20,11)	96.48 (94.43 to 98.54)	100 (95.52 to 100)	100 (92.01 to 100)	

Statistical analyses

Statistical analysis title	Percent of Participants with Graft Survival
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[127]
P-value	= 0.3132
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	1.69
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	0.28
upper limit	3.11
Variability estimate	Standard error of the mean
Dispersion value	1.68

Notes:

[127] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percent of Participants with Graft Survival
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[128]
P-value	= 0.3132
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	1.69
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	0.28
upper limit	3.11

Variability estimate	Standard error of the mean
Dispersion value	1.68

Notes:

[128] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percent of Participants with Graft Survival

Statistical analysis description:

Month 36

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[129]
P-value	= 0.1503
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.52
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.46
upper limit	5.57
Variability estimate	Standard error of the mean
Dispersion value	2.44

Notes:

[129] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percent of Participants with Graft Survival

Statistical analysis description:

Month 36

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[130]
P-value	= 0.1503
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.52
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.46
upper limit	5.57
Variability estimate	Standard error of the mean
Dispersion value	2.44

Notes:

[130] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percent of Participants with Graft Survival

Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[131]
P-value	= 0.1503
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.52
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.46
upper limit	5.57
Variability estimate	Standard error of the mean
Dispersion value	2.44

Notes:

[131] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percent of Participants with Graft Survival
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[132]
P-value	= 0.1503
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.52
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.46
upper limit	5.57
Variability estimate	Standard error of the mean
Dispersion value	2.44

Notes:

[132] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percent of Participants with Graft Survival
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[133]
P-value	= 0.1503
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.52
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.46
upper limit	5.57
Variability estimate	Standard error of the mean
Dispersion value	2.44

Notes:

[133] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percent of Participants with Graft Survival
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[134]
P-value	= 0.1503
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.52
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.46
upper limit	5.57
Variability estimate	Standard error of the mean
Dispersion value	2.44

Notes:

[134] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percent of Participants with Graft Survival
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[135]
P-value	= 0.1503
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.52

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.46
upper limit	5.57
Variability estimate	Standard error of the mean
Dispersion value	2.44

Notes:

[135] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percent of Participants with Graft Survival
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[136]
P-value	= 0.1503
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.52
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.46
upper limit	5.57
Variability estimate	Standard error of the mean
Dispersion value	2.44

Notes:

[136] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percent of Participants with Graft Survival
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[137]
P-value	= 0.1503
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.52
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.46
upper limit	5.57
Variability estimate	Standard error of the mean
Dispersion value	2.44

Notes:

[137] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percent of Participants with Graft Survival
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[138]
P-value	= 0.1503
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.52
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.46
upper limit	5.57
Variability estimate	Standard error of the mean
Dispersion value	2.44

Notes:

[138] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percent of Participants with Graft Survival
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[139]
P-value	= 0.1503
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.52
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.46
upper limit	5.57
Variability estimate	Standard error of the mean
Dispersion value	2.44

Notes:

[139] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percent of Participants with Graft Survival
Statistical analysis description:	
Month 66	

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[140]
P-value	= 0.1503
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.52
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.46
upper limit	5.57
Variability estimate	Standard error of the mean
Dispersion value	2.44

Notes:

[140] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percent of Participants with Graft Survival

Statistical analysis description:

Month 72

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[141]
P-value	= 0.1503
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.52
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.46
upper limit	5.57
Variability estimate	Standard error of the mean
Dispersion value	2.44

Notes:

[141] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percent of Participants with Graft Survival

Statistical analysis description:

Month 72

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[142]
P-value	= 0.1503
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.52
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.46
upper limit	5.57
Variability estimate	Standard error of the mean
Dispersion value	2.44

Notes:

[142] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Secondary: Kaplan-Meier Analysis of Percentage of Participants Surviving by Visit

End point title	Kaplan-Meier Analysis of Percentage of Participants Surviving by Visit

End point description:

The 'Number' and 'Confidence Interval 60%' columns represent cumulative proportions and 60% CIs as estimated from the fitted Kaplan-Meier curves for each treatment at scheduled visits. Included data up to 2 months postdose in the clinical Follow-up visit.

End point type	Secondary

End point timeframe:

Months 12, 15, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: Percentage of Participants				
number (confidence interval 60%)				
Month 12 (n=64,60,54)	100 (98.58 to 100)	100 (98.48 to 100)	100 (98.32 to 100)	
Month 15 (n=64,60,53)	100 (98.58 to 100)	100 (98.48 to 100)	98.15 (96.6 to 99.69)	
Month 18 (n=61,59,51)	98.41 (97.09 to 99.74)	100 (98.46 to 100)	98.15 (96.6 to 99.69)	
Month 24 (n=59,58,44)	98.41 (97.09 to 99.74)	100 (98.43 to 100)	94.22 (91.49 to 96.95)	
Month 30 (n=55,42,31)	98.41 (97.09 to 99.74)	100 (97.84 to 100)	94.22 (91.49 to 96.95)	
Month 36 (n=53,32,16)	98.41 (97.09 to 99.74)	100 (97.18 to 100)	90.97 (87.21 to 94.73)	
Month 42 (n=45,32,15)	96.27 (94.07 to 98.48)	100 (97.18 to 100)	90.97 (87.21 to 94.73)	
Month 48 (n=44,32,15)	96.27 (94.07 to 98.48)	100 (97.18 to 100)	90.97 (87.21 to 94.73)	

Month 54 (n=43,31,14)	94.09 (91.27 to 96.9)	100 (97.09 to 100)	90.97 (87.21 to 94.73)	
Month 60 (n=40,26,13)	94.09 (91.27 to 96.9)	100 (96.54 to 100)	90.97 (87.21 to 94.73)	
Month 66 (n=35,23,11)	94.09 (91.27 to 96.9)	100 (96.09 to 100)	90.97 (87.21 to 94.73)	
Month 72 (n=31,20,11)	94.09 (91.27 to 96.9)	100 (95.52 to 100)	90.97 (87.21 to 94.73)	

Statistical analyses

Statistical analysis title	Percentage of Participants Surviving by Visit
Statistical analysis description:	
Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[143]
P-value	= 0.3128
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-1.85
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-3.4
upper limit	-0.31
Variability estimate	Standard error of the mean
Dispersion value	1.83

Notes:

[143] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[144]
P-value	= 0.3134
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	1.59
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	0.26
upper limit	2.91

Variability estimate	Standard error of the mean
Dispersion value	1.57

Notes:

[144] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit

Statistical analysis description:

Month 18

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[145]
P-value	= 0.9129
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-0.26
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-2.3
upper limit	1.77
Variability estimate	Standard error of the mean
Dispersion value	2.42

Notes:

[145] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit

Statistical analysis description:

Month 24

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[146]
P-value	= 0.3134
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	1.59
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	0.26
upper limit	2.91
Variability estimate	Standard error of the mean
Dispersion value	1.57

Notes:

[146] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit

Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[147]
P-value	= 0.2447
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-4.19
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-7.23
upper limit	-1.16
Variability estimate	Standard error of the mean
Dispersion value	3.61

Notes:

[147] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[148]
P-value	= 0.3134
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	1.59
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	0.26
upper limit	2.91
Variability estimate	Standard error of the mean
Dispersion value	1.57

Notes:

[148] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[149]
P-value	= 0.2447
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-4.19
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-7.23
upper limit	-1.16
Variability estimate	Standard error of the mean
Dispersion value	3.61

Notes:

[149] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[150]
P-value	= 0.3134
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	1.59
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	0.26
upper limit	2.91
Variability estimate	Standard error of the mean
Dispersion value	1.57

Notes:

[150] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[151]
P-value	= 0.1164
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-7.44

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-11.43
upper limit	-3.45
Variability estimate	Standard error of the mean
Dispersion value	4.74

Notes:

[151] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit

Statistical analysis description:

Month 42

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[152]
P-value	= 0.1545
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.73
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.52
upper limit	5.93
Variability estimate	Standard error of the mean
Dispersion value	2.62

Notes:

[152] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit

Statistical analysis description:

Month 42

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[153]
P-value	= 0.3061
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-5.3
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-9.66
upper limit	-0.94
Variability estimate	Standard error of the mean
Dispersion value	5.18

Notes:

[153] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[154]
P-value	= 0.1545
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	3.73
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.52
upper limit	5.93
Variability estimate	Standard error of the mean
Dispersion value	2.62

Notes:

[154] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[155]
P-value	= 0.3061
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-5.3
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-9.66
upper limit	-0.94
Variability estimate	Standard error of the mean
Dispersion value	5.18

Notes:

[155] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit
Statistical analysis description:	
Month 54	

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[156]
P-value	= 0.0774
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	5.91
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	3.1
upper limit	8.73
Variability estimate	Standard error of the mean
Dispersion value	3.35

Notes:

[156] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit

Statistical analysis description:

Month 54

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[157]
P-value	= 0.5772
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-3.12
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-7.82
upper limit	1.59
Variability estimate	Standard error of the mean
Dispersion value	5.59

Notes:

[157] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit

Statistical analysis description:

Month 60

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[158]
P-value	= 0.0774
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	5.91
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	3.1
upper limit	8.73
Variability estimate	Standard error of the mean
Dispersion value	3.35

Notes:

[158] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit

Statistical analysis description:

Month 60

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[159]
P-value	= 0.5772
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-3.12
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-7.82
upper limit	1.59
Variability estimate	Standard error of the mean
Dispersion value	5.59

Notes:

[159] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit

Statistical analysis description:

Month 66

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[160]
P-value	= 0.0774
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	5.91

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	3.1
upper limit	8.73
Variability estimate	Standard error of the mean
Dispersion value	3.35

Notes:

[160] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit

Statistical analysis description:

Month 66

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[161]
P-value	= 0.5772
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-3.12
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-7.82
upper limit	1.59
Variability estimate	Standard error of the mean
Dispersion value	5.59

Notes:

[161] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit

Statistical analysis description:

Month 72

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[162]
P-value	= 0.0774
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	5.91
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	3.1
upper limit	8.73
Variability estimate	Standard error of the mean
Dispersion value	3.35

Notes:

[162] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Statistical analysis title	Percentage of Participants Surviving by Visit
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[163]
P-value	= 0.5772
Method	Wald Test
Parameter estimate	Mean difference (final values)
Point estimate	-3.12
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-7.82
upper limit	1.59
Variability estimate	Standard error of the mean
Dispersion value	5.59

Notes:

[163] - Point estimates, lower and upper confidence limits represent percentages. The mean difference and standard error of the mean is the percentage difference and standard error of the percentage difference.

Secondary: Percentage of Participants Discontinuing from the Study

End point title	Percentage of Participants Discontinuing from the Study
End point description:	
Discontinuations were due to any reason including those occurring as a result of protocol Amendments 3 and 4.	
End point type	Secondary
End point timeframe:	
Months 12 through 72.	

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: Percentage of Participants				
number (not applicable)	43.8	75	85.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Least Squares (LS) Means of Total Serum Cholesterol Levels (milligrams per deciliter [mg/dL]) by Visit

End point title	Least Squares (LS) Means of Total Serum Cholesterol Levels (milligrams per deciliter [mg/dL]) by Visit

End point description:

Model contained treatment, visit and treatment by visit interaction as fixed effects and Baseline (predose in Study A3921030) as a covariate. A first-order autoregressive variance-covariance structure was used.

End point type	Secondary

End point timeframe:

Months 15, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: mg/dL				
least squares mean (standard error)				
Month 15 (n=59,59,49)	199.14 (± 5.71)	213.49 (± 5.81)	196.27 (± 6.29)	
Month 18 (n=59,59,49)	200.51 (± 5.75)	212.67 (± 5.82)	193.5 (± 6.34)	
Month 24 (n=58,54,40)	198.78 (± 5.82)	212.3 (± 5.98)	185.57 (± 6.8)	
Month 30 (n=52,37,26)	193.99 (± 6.05)	211.59 (± 6.84)	202.73 (± 8.08)	
Month 36 (n=51,32,15)	198.62 (± 6.17)	211.14 (± 7.51)	192.97 (± 10.37)	
Month 42 (n=44,31,15)	200.36 (± 6.52)	220.29 (± 7.83)	208.77 (± 11.13)	
Month 48 (n=42,30,14)	196.56 (± 6.74)	228.83 (± 7.98)	188.83 (± 11.66)	
Month 54 (n=41,31,13)	193.66 (± 6.87)	222.86 (± 7.98)	183.17 (± 12.06)	
Month 60 (n=37,23,12)	190.1 (± 7.17)	220.47 (± 8.85)	184.14 (± 12.53)	
Month 66 (n=34,20,11)	191 (± 7.47)	218.77 (± 9.47)	189.15 (± 13.14)	
Month 72 (n=31,17,11)	188.74 (± 7.82)	209.12 (± 10.26)	182.6 (± 13.36)	

Statistical analyses

Statistical analysis title	LS Means of Total Serum Cholesterol Levels

Statistical analysis description:

Month 15

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[164]
P-value	= 0.0786
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	14.35
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	7.49
upper limit	21.22
Variability estimate	Standard error of the mean
Dispersion value	8.15

Notes:

[164] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[165]
P-value	= 0.736
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2.87
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-10.03
upper limit	4.29
Variability estimate	Standard error of the mean
Dispersion value	8.5

Notes:

[165] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[166]
P-value	= 0.1377
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	12.16

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	5.27
upper limit	19.05
Variability estimate	Standard error of the mean
Dispersion value	8.19

Notes:
[166] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[167]
P-value	= 0.4131
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-7.01
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-14.21
upper limit	0.2
Variability estimate	Standard error of the mean
Dispersion value	8.56

Notes:
[167] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[168]
P-value	= 0.1057
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	13.52
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	6.49
upper limit	20.55
Variability estimate	Standard error of the mean
Dispersion value	8.35

Notes:
[168] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[169]
P-value	= 0.1402
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-13.21
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-20.75
upper limit	-5.68
Variability estimate	Standard error of the mean
Dispersion value	8.95

Notes:
[169] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[170]
P-value	= 0.0542
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	17.6
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	9.91
upper limit	25.29
Variability estimate	Standard error of the mean
Dispersion value	9.13

Notes:
[170] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[171]
P-value	= 0.3866
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	8.74
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	0.24
upper limit	17.24
Variability estimate	Standard error of the mean
Dispersion value	10.09

Notes:

[171] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[172]
P-value	= 0.1981
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	12.52
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	4.33
upper limit	20.71
Variability estimate	Standard error of the mean
Dispersion value	9.72

Notes:

[172] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[173]
P-value	= 0.6397
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-5.65

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-15.81
upper limit	4.51
Variability estimate	Standard error of the mean
Dispersion value	12.07

Notes:
[173] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[174]
P-value	= 0.0508
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	19.93
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	11.35
upper limit	28.51
Variability estimate	Standard error of the mean
Dispersion value	10.19

Notes:
[174] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[175]
P-value	= 0.5143
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	8.42
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-2.45
upper limit	19.28
Variability estimate	Standard error of the mean
Dispersion value	12.9

Notes:
[175] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[176]
P-value	= 0.0021
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	32.26
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	23.46
upper limit	41.06
Variability estimate	Standard error of the mean
Dispersion value	10.45

Notes:
[176] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[177]
P-value	= 0.5661
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-7.73
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-19.07
upper limit	3.61
Variability estimate	Standard error of the mean
Dispersion value	13.47

Notes:
[177] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[178]
P-value	= 0.0057
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	29.2
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	20.33
upper limit	38.08
Variability estimate	Standard error of the mean
Dispersion value	10.54

Notes:

[178] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[179]
P-value	= 0.4504
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-10.49
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-22.18
upper limit	1.21
Variability estimate	Standard error of the mean
Dispersion value	13.89

Notes:

[179] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[180]
P-value	= 0.0078
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	30.37

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	20.78
upper limit	39.96
Variability estimate	Standard error of the mean
Dispersion value	11.39

Notes:
[180] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[181]
P-value	= 0.6802
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-5.95
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-18.11
upper limit	6.2
Variability estimate	Standard error of the mean
Dispersion value	14.44

Notes:
[181] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[182]
P-value	= 0.0216
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	27.78
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	17.61
upper limit	37.95
Variability estimate	Standard error of the mean
Dispersion value	12.08

Notes:
[182] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[183]
P-value	= 0.9026
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.85
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-14.58
upper limit	10.88
Variability estimate	Standard error of the mean
Dispersion value	15.12

Notes:
[183] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[184]
P-value	= 0.1146
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	20.38
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	9.51
upper limit	31.24
Variability estimate	Standard error of the mean
Dispersion value	12.91

Notes:
[184] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Cholesterol Levels
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[185]
P-value	= 0.6918
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-6.14
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-19.18
upper limit	6.9
Variability estimate	Standard error of the mean
Dispersion value	15.48

Notes:

[185] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Secondary: LS Means of Total Serum Low Density Lipoprotein (LDL) Cholesterol Levels (mg/dL) by Visit

End point title	LS Means of Total Serum Low Density Lipoprotein (LDL) Cholesterol Levels (mg/dL) by Visit

End point description:

Model contained treatment, visit and treatment by visit interaction as fixed effects and Baseline (predose in Study A3921030) as a covariate. A first-order autoregressive variance-covariance structure was used.

End point type	Secondary

End point timeframe:

Months 15, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: mg/dL				
least squares mean (standard error)				
Month 15 (n=54,54,48)	113.09 (± 4.6)	119.71 (± 4.68)	108.72 (± 4.94)	
Month 18 (n=56,54,49)	112.82 (± 4.58)	119.36 (± 4.69)	109.87 (± 4.94)	
Month 24 (n=55,49,40)	111.14 (± 4.64)	119.15 (± 4.83)	104.63 (± 5.29)	
Month 30 (n=49,36,25)	106.79 (± 4.84)	125.24 (± 5.43)	112.44 (± 6.36)	
Month 36 (n=47,31,15)	112.81 (± 4.97)	123.27 (± 5.95)	109.54 (± 8.1)	
Month 42 (n=42,27,15)	110.98 (± 5.21)	122.51 (± 6.39)	121.74 (± 8.67)	
Month 48 (n=41,27,14)	109.03 (± 5.35)	127.65 (± 6.48)	105.59 (± 9.08)	
Month 54 (n=40,28,13)	107.21 (± 5.44)	128.39 (± 6.45)	96.6 (± 9.39)	

Month 60 (n=36,21,12)	105.37 (± 5.66)	123.71 (± 7.18)	97.79 (± 9.75)	
Month 66 (n=32,19,11)	104.31 (± 5.95)	123.74 (± 7.64)	102.44 (± 10.23)	
Month 72 (n=30,16,11)	109.18 (± 6.19)	116.17 (± 8.27)	96.11 (± 10.4)	

Statistical analyses

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[186]
P-value	= 0.3139
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	6.62
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.09
upper limit	12.14
Variability estimate	Standard error of the mean
Dispersion value	6.57

Notes:

[186] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[187]
P-value	= 0.5176
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-4.37
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-10.06
upper limit	1.31
Variability estimate	Standard error of the mean
Dispersion value	6.75

Notes:
[187] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[188]
P-value	= 0.3191
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	6.54
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.02
upper limit	12.06
Variability estimate	Standard error of the mean
Dispersion value	6.56

Notes:
[188] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[189]
P-value	= 0.6608
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2.95
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-8.62
upper limit	2.71
Variability estimate	Standard error of the mean
Dispersion value	6.73

Notes:
[189] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[190]
P-value	= 0.2319
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	8.02
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	2.37
upper limit	13.66
Variability estimate	Standard error of the mean
Dispersion value	6.7

Notes:

[190] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[191]
P-value	= 0.3554
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-6.5
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-12.43
upper limit	-0.58
Variability estimate	Standard error of the mean
Dispersion value	7.04

Notes:

[191] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[192]
P-value	= 0.0113
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	18.45

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	12.33
upper limit	24.57
Variability estimate	Standard error of the mean
Dispersion value	7.27

Notes:
[192] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[193]
P-value	= 0.479
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	5.66
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-1.07
upper limit	12.39
Variability estimate	Standard error of the mean
Dispersion value	7.99

Notes:
[193] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[194]
P-value	= 0.1776
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	10.46
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	3.93
upper limit	16.99
Variability estimate	Standard error of the mean
Dispersion value	7.75

Notes:
[194] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[195]
P-value	= 0.7307
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-3.27
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-11.27
upper limit	4.73
Variability estimate	Standard error of the mean
Dispersion value	9.5

Notes:
[195] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[196]
P-value	= 0.1625
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	11.53
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	4.59
upper limit	18.48
Variability estimate	Standard error of the mean
Dispersion value	8.25

Notes:
[196] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[197]
P-value	= 0.2876
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	10.77
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	2.25
upper limit	19.29
Variability estimate	Standard error of the mean
Dispersion value	10.12

Notes:

[197] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[198]
P-value	= 0.027
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	18.62
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	11.54
upper limit	25.7
Variability estimate	Standard error of the mean
Dispersion value	8.41

Notes:

[198] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[199]
P-value	= 0.7444
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-3.44

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-12.31
upper limit	5.44
Variability estimate	Standard error of the mean
Dispersion value	10.54

Notes:
[199] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[200]
P-value	= 0.0122
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	21.18
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	14.08
upper limit	28.29
Variability estimate	Standard error of the mean
Dispersion value	8.44

Notes:
[200] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[201]
P-value	= 0.3288
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-10.61
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-19.75
upper limit	-1.47
Variability estimate	Standard error of the mean
Dispersion value	10.86

Notes:
[201] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[202]
P-value	= 0.0453
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	18.34
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	10.63
upper limit	26.05
Variability estimate	Standard error of the mean
Dispersion value	9.15

Notes:
[202] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[203]
P-value	= 0.5016
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-7.59
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-17.09
upper limit	1.91
Variability estimate	Standard error of the mean
Dispersion value	11.28

Notes:
[203] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[204]
P-value	= 0.0453
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	19.43
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	11.27
upper limit	27.59
Variability estimate	Standard error of the mean
Dispersion value	9.69

Notes:
[204] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholsterol Levels
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[205]
P-value	= 0.8747
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.87
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-11.83
upper limit	8.1
Variability estimate	Standard error of the mean
Dispersion value	11.84

Notes:
[205] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[206]
P-value	= 0.4997
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	6.98

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-1.72
upper limit	15.69
Variability estimate	Standard error of the mean
Dispersion value	10.34

Notes:

[206] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum LDL Cholesterol Levels

Statistical analysis description:

Month 72

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[207]
P-value	= 0.2804
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-13.07
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-23.26
upper limit	-2.88
Variability estimate	Standard error of the mean
Dispersion value	12.1

Notes:

[207] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Secondary: LS Means of Total Serum High Density Lipoprotein (HDL) Cholesterol Levels (mg/dL) by Visit

End point title	LS Means of Total Serum High Density Lipoprotein (HDL) Cholesterol Levels (mg/dL) by Visit

End point description:

Model contained treatment, visit and treatment by visit interaction as fixed effects and Baseline (predose in Study A3921030) as a covariate. A first-order autoregressive variance-covariance structure was used.

End point type	Secondary

End point timeframe:

Months 15, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: mg/dL				
least squares mean (standard error)				
Month 15 (n=59,59,49)	49.88 (± 1.75)	59.67 (± 1.79)	55.2 (± 1.93)	
Month 18 (n=59,59,49)	50.47 (± 1.77)	59.87 (± 1.79)	55.78 (± 1.95)	
Month 24 (n=58,54,40)	51.47 (± 1.79)	59.84 (± 1.84)	53.52 (± 2.08)	
Month 30 (n=52,37,26)	49.55 (± 1.85)	60.45 (± 2.1)	53.84 (± 2.47)	
Month 36 (n=51,32,15)	50.46 (± 1.89)	59.92 (± 2.3)	54.59 (± 3.17)	
Month 42 (n=44,31,15)	53.24 (± 2)	59.32 (± 2.4)	58.59 (± 3.41)	
Month 48 (n=42,30,14)	54.59 (± 2.07)	61.67 (± 2.45)	53.55 (± 3.57)	
Month 54 (n=41,31,13)	54.55 (± 2.11)	60.18 (± 2.45)	52.38 (± 3.7)	
Month 60 (n=37,23,12)	54.72 (± 2.2)	60.2 (± 2.71)	58.98 (± 3.84)	
Month 66 (n=34,20,11)	54.69 (± 2.29)	62.12 (± 2.9)	56.08 (± 4.03)	
Month 72 (31,17,11)	52.8 (± 2.4)	58.8 (± 3.14)	54.93 (± 4.1)	

Statistical analyses

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description: Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[208]
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	9.79
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	7.68
upper limit	11.9
Variability estimate	Standard error of the mean
Dispersion value	2.5

Notes:

[208] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description: Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[209]
P-value	= 0.0418
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	5.32
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	3.12
upper limit	7.52
Variability estimate	Standard error of the mean
Dispersion value	2.61

Notes:

[209] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[210]
P-value	= 0.0002
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	9.4
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	7.28
upper limit	11.51
Variability estimate	Standard error of the mean
Dispersion value	2.51

Notes:

[210] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[211]
P-value	= 0.0437
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	5.3

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	3.09
upper limit	7.51
Variability estimate	Standard error of the mean
Dispersion value	2.63

Notes:
[211] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[212]
P-value	= 0.0011
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	8.37
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	6.21
upper limit	10.53
Variability estimate	Standard error of the mean
Dispersion value	2.56

Notes:
[212] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[213]
P-value	= 0.4565
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.04
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-0.27
upper limit	4.36
Variability estimate	Standard error of the mean
Dispersion value	2.75

Notes:
[213] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[214]
P-value	= 0.0001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	10.9
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	8.54
upper limit	13.26
Variability estimate	Standard error of the mean
Dispersion value	2.8

Notes:
[214] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[215]
P-value	= 0.1654
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	4.29
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.69
upper limit	6.89
Variability estimate	Standard error of the mean
Dispersion value	3.09

Notes:
[215] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[216]
P-value	= 0.0015
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	9.45
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	6.95
upper limit	11.96
Variability estimate	Standard error of the mean
Dispersion value	2.98

Notes:

[216] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[217]
P-value	= 0.2636
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	4.13
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.02
upper limit	7.23
Variability estimate	Standard error of the mean
Dispersion value	3.69

Notes:

[217] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[218]
P-value	= 0.052
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	6.08

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	3.45
upper limit	8.71
Variability estimate	Standard error of the mean
Dispersion value	3.12

Notes:
[218] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[219]
P-value	= 0.176
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	5.35
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	2.02
upper limit	8.67
Variability estimate	Standard error of the mean
Dispersion value	3.95

Notes:
[219] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[220]
P-value	= 0.0274
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	7.08
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	4.38
upper limit	9.77
Variability estimate	Standard error of the mean
Dispersion value	3.2

Notes:
[220] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[221]
P-value	= 0.8018
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.04
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-4.51
upper limit	2.44
Variability estimate	Standard error of the mean
Dispersion value	4.13

Notes:
[221] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[222]
P-value	= 0.0819
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	5.63
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	2.91
upper limit	8.35
Variability estimate	Standard error of the mean
Dispersion value	3.23

Notes:
[222] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[223]
P-value	= 0.6103
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2.17
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-5.75
upper limit	1.41
Variability estimate	Standard error of the mean
Dispersion value	4.26

Notes:

[223] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[224]
P-value	= 0.1168
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	5.48
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	2.54
upper limit	8.41
Variability estimate	Standard error of the mean
Dispersion value	3.49

Notes:

[224] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[225]
P-value	= 0.3357
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	4.26

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	0.54
upper limit	7.99
Variability estimate	Standard error of the mean
Dispersion value	4.43

Notes:
[225] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description: Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[226]
P-value	= 0.0448
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	7.42
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	4.31
upper limit	10.54
Variability estimate	Standard error of the mean
Dispersion value	3.7

Notes:
[226] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description: Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[227]
P-value	= 0.7642
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.39
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-2.51
upper limit	5.29
Variability estimate	Standard error of the mean
Dispersion value	4.64

Notes:
[227] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[228]
P-value	= 0.1295
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	5.99
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	2.67
upper limit	9.32
Variability estimate	Standard error of the mean
Dispersion value	3.95

Notes:
[228] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum HDL Cholesterol Levels
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[229]
P-value	= 0.654
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.13
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-1.87
upper limit	6.13
Variability estimate	Standard error of the mean
Dispersion value	4.75

Notes:
[229] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Secondary: LS Means of Total Serum Triglycerides (mg/dL) by Visit

End point title	LS Means of Total Serum Triglycerides (mg/dL) by Visit

End point description:

Model contained treatment, visit and treatment by visit interaction as fixed effects and Baseline (predose in Study A3921030) as a covariate. A first-order autoregressive variance-covariance structure

was used.

End point type	Secondary

End point timeframe:
Month 15, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: mg/dL				
least squares mean (standard error)				
Month 15 (n=59,59,49)	177.33 (± 13.66)	171.21 (± 13.94)	167.38 (± 15.07)	
Month 18 (n=59,59,49)	181.92 (± 13.74)	163.26 (± 13.97)	145.05 (± 15.18)	
Month 24 (n=58,54,40)	183.79 (± 13.93)	162.8 (± 14.33)	142.07 (± 16.23)	
Month 30 (n=52,37,26)	182.49 (± 14.44)	137.05 (± 16.28)	178.56 (± 19.18)	
Month 36 (n=51,32,15)	174.01 (± 14.73)	145.27 (± 17.85)	152.98 (± 24.5)	
Month 42 (n=44,31,15)	178.93 (± 15.55)	183.09 (± 18.64)	148.62 (± 26.42)	
Month 48 (n=42,30,14)	166.38 (± 16.08)	196.86 (± 19.04)	156.12 (± 27.76)	
Month 54 (n=41,31,13)	163.57 (± 16.41)	169.18 (± 19.07)	178.24 (± 28.75)	
Month 60 (n=37,23,12)	156.27 (± 17.1)	173.2 (± 21.06)	142.27 (± 29.89)	
Month 66 (n=34,20,11)	165.83 (± 17.82)	174.19 (± 22.54)	158.73 (± 31.35)	
Month 72 (n=31,17,11)	143.03 (± 18.63)	165.1 (± 24.4)	161.28 (± 31.94)	

Statistical analyses

Statistical analysis title	LS Means of Total Serum Triglycerides

Statistical analysis description:
Month 15

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[230]
P-value	= 0.7543
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-6.11

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-22.55
upper limit	10.33
Variability estimate	Standard error of the mean
Dispersion value	19.53

Notes:
[230] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[231]
P-value	= 0.6249
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-9.95
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-27.07
upper limit	7.17
Variability estimate	Standard error of the mean
Dispersion value	20.33

Notes:
[231] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[232]
P-value	= 0.3415
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-18.66
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-35.17
upper limit	-2.15
Variability estimate	Standard error of the mean
Dispersion value	19.61

Notes:
[232] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[233]
P-value	= 0.072
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-36.86
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-54.1
upper limit	-19.63
Variability estimate	Standard error of the mean
Dispersion value	20.47

Notes:
[233] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[234]
P-value	= 0.2937
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-21
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-37.83
upper limit	-4.17
Variability estimate	Standard error of the mean
Dispersion value	19.99

Notes:
[234] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[235]
P-value	= 0.0512
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-41.72
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-59.72
upper limit	-23.73
Variability estimate	Standard error of the mean
Dispersion value	21.38

Notes:

[235] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[236]
P-value	= 0.037
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-45.43
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-63.75
upper limit	-27.11
Variability estimate	Standard error of the mean
Dispersion value	21.76

Notes:

[236] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[237]
P-value	= 0.8701
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-3.92

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-24.13
upper limit	16.28
Variability estimate	Standard error of the mean
Dispersion value	24

Notes:
[237] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description: Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[238]
P-value	= 0.2146
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-28.75
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-48.24
upper limit	-9.25
Variability estimate	Standard error of the mean
Dispersion value	23.15

Notes:
[238] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description: Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[239]
P-value	= 0.462
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-21.03
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-45.09
upper limit	3.03
Variability estimate	Standard error of the mean
Dispersion value	28.58

Notes:
[239] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[240]
P-value	= 0.8639
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	4.16
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-16.28
upper limit	24.6
Variability estimate	Standard error of the mean
Dispersion value	24.28

Notes:
[240] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[241]
P-value	= 0.323
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-30.3
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-56.11
upper limit	-4.5
Variability estimate	Standard error of the mean
Dispersion value	30.65

Notes:
[241] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[242]
P-value	= 0.2214
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	30.49
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	9.51
upper limit	51.47
Variability estimate	Standard error of the mean
Dispersion value	24.92

Notes:
[242] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[243]
P-value	= 0.7492
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-10.25
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-37.26
upper limit	16.75
Variability estimate	Standard error of the mean
Dispersion value	32.08

Notes:
[243] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[244]
P-value	= 0.8236
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	5.61

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-15.57
upper limit	26.79
Variability estimate	Standard error of the mean
Dispersion value	25.15

Notes:
[244] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[245]
P-value	= 0.6578
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	14.67
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-13.2
upper limit	42.54
Variability estimate	Standard error of the mean
Dispersion value	33.1

Notes:
[245] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[246]
P-value	= 0.5326
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	16.93
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-5.9
upper limit	39.76
Variability estimate	Standard error of the mean
Dispersion value	27.12

Notes:
[246] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[247]
P-value	= 0.6845
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-14
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-42.99
upper limit	15
Variability estimate	Standard error of the mean
Dispersion value	34.44

Notes:
[247] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[248]
P-value	= 0.7713
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	8.35
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-15.83
upper limit	32.54
Variability estimate	Standard error of the mean
Dispersion value	28.73

Notes:
[248] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[249]
P-value	= 0.8438
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-7.11
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-37.47
upper limit	23.26
Variability estimate	Standard error of the mean
Dispersion value	36.06

Notes:
[249] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[250]
P-value	= 0.4724
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	22.06
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-3.78
upper limit	47.91
Variability estimate	Standard error of the mean
Dispersion value	30.7

Notes:
[250] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Total Serum Triglycerides
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[251]
P-value	= 0.6218
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	18.25

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-12.89
upper limit	49.38
Variability estimate	Standard error of the mean
Dispersion value	36.98

Notes:

[251] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Secondary: Mean Absolute Neutrophil Counts (ANC) (kelvin per millimeter cubed [K/mm^3]) by Visit

End point title	Mean Absolute Neutrophil Counts (ANC) (kelvin per millimeter cubed [K/mm^3]) by Visit

End point description:

Follow-up visit included Month 74 visit for completers and 2-month postdose visit for early withdrawals.

End point type	Secondary

End point timeframe:

Months 15, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72 and Follow-up

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: k/mm^3				
arithmetic mean (standard deviation)				
Month 15 (n=55,56,47)	4.53 (± 1.82)	4.23 (± 1.79)	4.33 (± 1.76)	
Month 18 (n=59,58,49)	4.59 (± 1.98)	3.87 (± 1.57)	4.83 (± 2.84)	
Month 24 (n=54,52,39)	4.62 (± 1.93)	3.99 (± 1.43)	4.38 (± 1.55)	
Month 30 (n=48,35,26)	4.69 (± 1.91)	3.48 (± 1.25)	4.55 (± 1.71)	
Month 36 (n=51,30,15)	4.48 (± 1.93)	3.72 (± 1.41)	4.62 (± 1.22)	
Month 42 (n=40,31,15)	4.3 (± 1.8)	3.9 (± 1.76)	4.49 (± 0.81)	
Month 48 (n=41,30,13)	3.86 (± 1.93)	3.47 (± 1.58)	3.86 (± 1.59)	
Month 54 (n=38,26,11)	4.11 (± 1.78)	3.42 (± 1.09)	4.27 (± 1.52)	
Month 60 (n=37,20,11)	4.3 (± 1.8)	3.97 (± 1.57)	4.01 (± 1.24)	
Month 66 (n=34,19,11)	4.53 (± 1.85)	3.86 (± 1.51)	4.28 (± 1.21)	
Month 72 (n=31,17,11)	4.33 (± 1.85)	3.44 (± 1.12)	4.73 (± 1.47)	
Follow-up (n=51,46,41)	4.65 (± 1.77)	3.75 (± 1.26)	4.37 (± 1.97)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Hemoglobin (Hgb) (grams per deciliter [g/dL]) by Visit

End point title	Mean Hemoglobin (Hgb) (grams per deciliter [g/dL]) by Visit

End point description:

Follow-up visit included Month 74 visit for completers and 2-month postdose visit for early withdrawals.

End point type	Secondary

End point timeframe:

Months 15, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72 and Follow-up

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: g/dL				
arithmetic mean (standard deviation)				
Month 15 (n=58,59,48)	13.2 (± 1.78)	13.14 (± 1.41)	13.35 (± 1.65)	
Month 18 (n=59,59,49)	13.15 (± 1.71)	13.31 (± 1.13)	13.5 (± 1.86)	
Month 24 (n=57,54,41)	13.35 (± 1.58)	13.58 (± 1.25)	13.58 (± 1.54)	
Month 30 (n=48,37,28)	13.21 (± 1.66)	13.66 (± 1.23)	13.82 (± 1.6)	
Month 36 (n=52,32,15)	13.3 (± 1.59)	13.91 (± 1.08)	13.44 (± 1.94)	
Month 42 (n=41,31,15)	13.24 (± 1.6)	13.99 (± 0.99)	13.67 (± 1.7)	
Month 48 (n=42,31,13)	13.05 (± 1.71)	14.01 (± 1.18)	13.28 (± 1.45)	
Month 54 (n=40,29,11)	13.22 (± 1.53)	13.98 (± 1.31)	13.6 (± 1.54)	
Month 60 (n=37,20,12)	13.29 (± 1.56)	14.4 (± 1.24)	13.41 (± 1.94)	
Month 66 (n=34,19,11)	13.02 (± 1.88)	14.62 (± 1.18)	13.42 (± 2.14)	
Month 72 (n=31,17,11)	13.1 (± 1.84)	14.22 (± 1.56)	13.23 (± 2.03)	
Follow-up (n=51,47,41)	12.49 (± 2.04)	13.23 (± 1.75)	13.72 (± 2.09)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Glycosylated Hemoglobin (HBA1c) (%) by Visit

End point title	Mean Glycosylated Hemoglobin (HBA1c) (%) by Visit

End point description:

HbA1c is a form of hemoglobin which is measured primarily to identify the average plasma glucose concentration over prolonged periods of time. The normal range for the HbA1c test is between 4 percent (%) and 5.6%. HbA1c levels between 5.7% and 6.4% indicate increased risk of diabetes and levels of 6.5% or higher indicate diabetes.

End point type	Secondary

End point timeframe:

Months 24, 36, 48, 60, 72

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: Percentage				
arithmetic mean (standard deviation)				
Month 24 n=(55,51,35)	6.35 (± 1.84)	6.16 (± 1.53)	6.37 (± 1.4)	
Month 36 (n=50,32,15)	6.16 (± 1.39)	5.92 (± 1.2)	6.69 (± 2.31)	
Month 48 (n=43,31,14)	6.15 (± 1.64)	6.16 (± 1.88)	6.59 (± 1.71)	
Month 60 (n=37,23,12)	6.36 (± 1.94)	6.26 (± 2.03)	6.28 (± 1.88)	
Month 72 (n=31,16,11)	6.52 (± 1.98)	6.34 (± 1.57)	6.33 (± 2.21)	

Statistical analyses

No statistical analyses for this end point

Secondary: LS Means of Fasting Serum Glucose Levels (mg/dL) by Visit

End point title	LS Means of Fasting Serum Glucose Levels (mg/dL) by Visit

End point description:

Model contained treatment, visit and treatment by visit interaction as fixed effects and Baseline (predose in Study A3921030) as a covariate. A compund symmetry variance-covariance structure was used.

End point type	Secondary

End point timeframe:

Months 15, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: mg/dL				
least squares mean (standard error)				
Month 15 (n=59,58,49)	104.42 (± 5.56)	102.1 (± 5.66)	107.18 (± 6.13)	
Month 18 (n=59,59,49)	113.01 (± 5.57)	106.17 (± 5.63)	107.56 (± 6.13)	
Month 24 (n=58,54,41)	112.23 (± 5.6)	107.81 (± 5.79)	102.47 (± 6.5)	
Month 30 (n=50,38,27)	105.27 (± 5.87)	108.01 (± 6.53)	107.7 (± 7.55)	
Month 36 (n=51,32,15)	95.88 (± 5.84)	106.27 (± 6.95)	106.03 (± 9.55)	
Month 42 (n=44,31,15)	107.1 (± 6.14)	114.43 (± 7.03)	94.16 (± 9.55)	
Month 48 (n=42,30,14)	101.14 (± 6.23)	109.86 (± 7.12)	104.07 (± 9.83)	
Month 54 (n=41,31,13)	114.5 (± 6.29)	110.62 (± 7.04)	127.38 (± 10.13)	

Month 60 (n=37,23,12)	109.75 (± 6.52)	106.64 (± 7.88)	107.49 (± 10.49)	
Month 66 (n=34,20,11)	104.42 (± 6.72)	103.25 (± 8.33)	108.55 (± 10.88)	
Month 72 (n=30,17,11)	107.01 (± 7.04)	105.22 (± 8.89)	99.82 (± 10.88)	

Statistical analyses

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[252]
P-value	= 0.7693
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2.33
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-9.01
upper limit	4.35
Variability estimate	Standard error of the mean
Dispersion value	7.93

Notes:

[252] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[253]
P-value	= 0.7396
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.75
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-4.22
upper limit	9.73
Variability estimate	Standard error of the mean
Dispersion value	8.28

Notes:
[253] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[254]
P-value	= 0.3881
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-6.84
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-13.51
upper limit	-0.17
Variability estimate	Standard error of the mean
Dispersion value	7.92

Notes:
[254] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[255]
P-value	= 0.5114
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-5.44
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-12.42
upper limit	1.53
Variability estimate	Standard error of the mean
Dispersion value	8.28

Notes:
[255] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[256]
P-value	= 0.5829
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-4.43
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-11.21
upper limit	2.36
Variability estimate	Standard error of the mean
Dispersion value	8.06

Notes:
[256] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[257]
P-value	= 0.2559
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-9.76
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-16.99
upper limit	-2.53
Variability estimate	Standard error of the mean
Dispersion value	8.58

Notes:
[257] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[258]
P-value	= 0.7548
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.74

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-4.65
upper limit	10.14
Variability estimate	Standard error of the mean
Dispersion value	8.78

Notes:
[258] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Match 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[259]
P-value	= 0.7998
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.43
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-5.63
upper limit	10.49
Variability estimate	Standard error of the mean
Dispersion value	9.57

Notes:
[259] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[260]
P-value	= 0.2531
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	10.39
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	2.74
upper limit	18.03
Variability estimate	Standard error of the mean
Dispersion value	9.08

Notes:
[260] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[261]
P-value	= 0.365
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	10.14
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	0.72
upper limit	19.57
Variability estimate	Standard error of the mean
Dispersion value	11.2

Notes:
[261] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[262]
P-value	= 0.4328
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	7.33
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-0.53
upper limit	15.19
Variability estimate	Standard error of the mean
Dispersion value	9.34

Notes:
[262] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[263]
P-value	= 0.2547
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-12.94
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-22.5
upper limit	-3.38
Variability estimate	Standard error of the mean
Dispersion value	11.35

Notes:

[263] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[264]
P-value	= 0.3572
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	8.72
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	0.75
upper limit	16.69
Variability estimate	Standard error of the mean
Dispersion value	9.46

Notes:

[264] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[265]
P-value	= 0.8009
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.94

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-6.86
upper limit	12.74
Variability estimate	Standard error of the mean
Dispersion value	11.64

Notes:
[265] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[266]
P-value	= 0.6814
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-3.88
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-11.82
upper limit	4.07
Variability estimate	Standard error of the mean
Dispersion value	9.44

Notes:
[266] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[267]
P-value	= 0.2803
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	12.88
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	2.84
upper limit	22.93
Variability estimate	Standard error of the mean
Dispersion value	11.93

Notes:
[267] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[268]
P-value	= 0.7613
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-3.11
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-11.72
upper limit	5.5
Variability estimate	Standard error of the mean
Dispersion value	10.23

Notes:
[268] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[269]
P-value	= 0.8554
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2.25
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-12.65
upper limit	8.15
Variability estimate	Standard error of the mean
Dispersion value	12.35

Notes:
[269] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[270]
P-value	= 0.9132
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.17
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-10.18
upper limit	7.84
Variability estimate	Standard error of the mean
Dispersion value	10.7

Notes:

[270] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[271]
P-value	= 0.7465
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	4.14
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-6.63
upper limit	14.9
Variability estimate	Standard error of the mean
Dispersion value	12.79

Notes:

[271] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[272]
P-value	= 0.8747
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.79

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-11.34
upper limit	7.76
Variability estimate	Standard error of the mean
Dispersion value	11.34

Notes:

[272] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Fasting Serum Glucose Levels

Statistical analysis description:

Month 72

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[273]
P-value	= 0.5793
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-7.19
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-18.1
upper limit	3.72
Variability estimate	Standard error of the mean
Dispersion value	12.96

Notes:

[273] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Secondary: Percentage of Participants by Proteinuria Category by Visit

End point title	Percentage of Participants by Proteinuria Category by Visit

End point description:

Proteinuria was defined as the presence of an excess of serum proteins in the urine. Normal value of proteinuria is below 0.15 grams per 24 hours (g/24 hr). Follow-up visit included Month 74 visit for completers and 2-month postdose visit for early withdrawals.

End point type	Secondary

End point timeframe:

Months 24, 36, 48, 60, 72 and Follow-up

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: Percentage of Participants				
number (not applicable)				
Month 24: >200 mg/day (n=51,47,36)	15.7	27.7	19.4	

Month 24: >500 mg/day (n=51,47,36)	3.9	6.4	8.3	
Month 24: >1500 mg/day (n=51,47,36)	2	2.1	5.6	
Month 24: >500 Increase from Baseline (n=51,47,36)	2	0	0	
Month 36: >200 mg/day (n=42,30,13)	14.3	26.7	15.4	
Month 36: >500 mg/day (n=42,30,13)	2.4	3.3	0	
Month 36: >1500 mg/day (n=42,30,13)	2.4	3.3	0	
Month 36: >500 Increase from Baseline (n=42,30,13)	0	0	0	
Month 48: >200 mg/day (n=36,29,12)	16.7	31	0	
Month 48: >500 mg/day (n=36,29,12)	5.6	17.2	0	
Month 48: >1500 mg/day (n=36,29,12)	2.8	6.9	0	
Month 48: >500 Increase in Baseline (n=36,29,12)	0	3.4	0	
Month 60: >200 mg/day (n=29,20,10)	10.3	20	10	
Month 60: >500 mg/day (n=29,20,10)	10.3	15	0	
Month 60: >1500 mg/day (n=29,20,10)	3.4	5	0	
Month 60: >500 Increase in Baseline (n=29,20,10)	0	5	0	
Month 72: >200 mg/day (n=22,15,9)	9.1	20	22.2	
Month 72: >500 mg/day (n=22,15,9)	4.5	20	11.1	
Month 72: >1500 mg/day (n=22,15,9)	0	13.3	0	
Month 72: >500 Increase in Baseline (n=22,15,9)	0	0	11.1	
Follow-up: >200 mg/day (n=46,34,39)	13	17.6	20.5	
Follow-up: >500 mg/day (n=46,34,39)	6.5	8.8	5.1	
Follow-up: >1500 mg/day (n=46,34,39)	2.2	5.9	2.6	
Follow-up: >500 Increase in Baseline (n=46,34,39)	0	0	2.6	

Statistical analyses

No statistical analyses for this end point

Secondary: LS Means of Estimated GFR Calculated Using the Nankivell Equation by Visit

End point title	LS Means of Estimated GFR Calculated Using the Nankivell Equation by Visit

End point description:

GFR: an index of kidney function. GFR described the flow rate of filtered fluid through the kidney. GFR was measured directly or estimated using established formulas. GFR was calculated using Nankivell formula, where: Creatinine clearance (mL/minute) = 6.7/serum creatinine (millimols per litre [mmol/L]) - serum urea (mmol/dL)/2 + actual body weight (kilograms [kg])/4 - 100/Height (metres)^2 + (35 for male or 25 for female). A normal GFR for adults is > 90 mL/min. Lower values indicate poor kidney function. A GFR <15 is consistent with kidney failure. Model contained treatment, visit and treatment by visit interaction as fixed effects. An unstructured variance-covariance structure was used.

End point type	Secondary

End point timeframe:

Month 15, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: minutes per milliliter (min/mL)				
least squares mean (standard error)				
Month 15 (n=59,59,50)	69.57 (± 1.95)	82.33 (± 2)	82.96 (± 2.13)	
Month 18 (n=59,59,50)	70.93 (± 2.09)	82.41 (± 2.15)	82.91 (± 2.28)	
Month 24 (n=58,54,41)	69.78 (± 2.09)	82.63 (± 2.15)	83.49 (± 2.32)	
Month 30 (n=51,37,27)	68.41 (± 2.28)	84.27 (± 2.46)	82.02 (± 2.73)	
Month 36 (n=51,32,15)	68.94 (± 2.44)	81.1 (± 2.66)	81.5 (± 3.14)	
Month 42 (n=44,31,15)	68.82 (± 2.29)	81.24 (± 2.49)	77.81 (± 2.98)	
Month 48 (n=42,30,14)	67.68 (± 2.54)	80.08 (± 2.79)	75.28 (± 3.46)	
Month 54 (n=41,31,13)	65.59 (± 2.69)	79.63 (± 2.98)	75.82 (± 3.88)	
Month 60 (n=37,24,12)	70.08 (± 2.46)	77.8 (± 2.77)	74.19 (± 3.51)	
Month 66 (n=34,20,11)	68.99 (± 2.8)	76.74 (± 3.17)	75.01 (± 4.01)	
Month 72 (n=30,17,11)	68.65 (± 3.39)	81.68 (± 4.01)	72.92 (± 5.1)	

Statistical analyses

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description: Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[274]
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	12.76
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	10.4
upper limit	15.11
Variability estimate	Standard error of the mean
Dispersion value	2.79

Notes:

[274] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description: Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[275]
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	13.39
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	10.96
upper limit	15.82
Variability estimate	Standard error of the mean
Dispersion value	2.88

Notes:
[275] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[276]
P-value	= 0.0002
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	11.48
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	8.95
upper limit	14
Variability estimate	Standard error of the mean
Dispersion value	3

Notes:
[276] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[277]
P-value	= 0.0002
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	11.98

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	9.37
upper limit	14.59
Variability estimate	Standard error of the mean
Dispersion value	3.09

Notes:
[277] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of estimated GFR - Nankivell Equation
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[278]
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	12.86
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	10.32
upper limit	15.39
Variability estimate	Standard error of the mean
Dispersion value	3

Notes:
[278] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[279]
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	13.71
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	11.08
upper limit	16.35
Variability estimate	Standard error of the mean
Dispersion value	3.12

Notes:
[279] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[280]
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	15.86
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	13.03
upper limit	18.69
Variability estimate	Standard error of the mean
Dispersion value	3.35

Notes:
[280] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[281]
P-value	= 0.0002
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	13.61
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	10.61
upper limit	16.61
Variability estimate	Standard error of the mean
Dispersion value	3.56

Notes:
[281] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[282]
P-value	= 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	12.17
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	9.12
upper limit	15.21
Variability estimate	Standard error of the mean
Dispersion value	3.61

Notes:
[282] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[283]
P-value	= 0.0019
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	12.56
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	9.2
upper limit	15.92
Variability estimate	Standard error of the mean
Dispersion value	3.98

Notes:
[283] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[284]
P-value	= 0.0004
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	12.42

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	9.56
upper limit	15.27
Variability estimate	Standard error of the mean
Dispersion value	3.38

Notes:
[284] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[285]
P-value	= 0.0182
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	8.99
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	5.81
upper limit	12.16
Variability estimate	Standard error of the mean
Dispersion value	3.76

Notes:
[285] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[286]
P-value	= 0.0013
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	12.4
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	9.22
upper limit	15.58
Variability estimate	Standard error of the mean
Dispersion value	3.77

Notes:
[286] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[287]
P-value	= 0.0782
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	7.6
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	3.99
upper limit	11.22
Variability estimate	Standard error of the mean
Dispersion value	4.29

Notes:
[287] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[288]
P-value	= 0.0007
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	14.04
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	10.64
upper limit	17.43
Variability estimate	Standard error of the mean
Dispersion value	4.02

Notes:
[288] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[289]
P-value	= 0.0322
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	10.23
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	6.24
upper limit	14.22
Variability estimate	Standard error of the mean
Dispersion value	4.72

Notes:

[289] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[290]
P-value	= 0.0399
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	7.72
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	4.59
upper limit	10.86
Variability estimate	Standard error of the mean
Dispersion value	3.7

Notes:

[290] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[291]
P-value	= 0.3391
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	4.11

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	0.49
upper limit	7.73
Variability estimate	Standard error of the mean
Dispersion value	4.28

Notes:
[291] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS means of Estimated GFR - Nankivell equation
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[292]
P-value	= 0.0702
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	7.75
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	4.17
upper limit	11.33
Variability estimate	Standard error of the mean
Dispersion value	4.23

Notes:
[292] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[293]
P-value	= 0.221
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	6.02
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	1.89
upper limit	10.15
Variability estimate	Standard error of the mean
Dispersion value	4.89

Notes:
[293] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description: Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[294]
P-value	= 0.015
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	13.03
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	8.59
upper limit	17.46
Variability estimate	Standard error of the mean
Dispersion value	5.25

Notes:
[294] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Nankivell Equation
Statistical analysis description: Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[295]
P-value	= 0.4875
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	4.27
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-0.91
upper limit	9.45
Variability estimate	Standard error of the mean
Dispersion value	6.13

Notes:
[295] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Secondary: LS Means of Estimated GFR Calculated Using the Cockcroft-Gault Equation by Visit

End point title	LS Means of Estimated GFR Calculated Using the Cockcroft-Gault Equation by Visit

End point description:

GFR: an index of kidney function. GFR described the flow rate of filtered fluid through the kidney. GFR was measured directly or estimated using established formulas. GFR was calculated using Cockcroft-Gault equation. GFR (mL/min) by Cockcroft-Gault equation= body weight (kg)*(140 minus age in years) divided by (72*serum creatinine [mg/dL]). For females value obtained was multiplied by 0.85. A normal GFR is >90 mL/min, although children and older people usually have a lower GFR. Lower values indicated poor kidney function. A GFR <15 mL/min indicated kidney failure. Model contained treatment, visit and treatment by visit interaction as fixed effects. An unstructured variance-covariance structure was used.

End point type	Secondary

End point timeframe:

Months 15, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: min/mL				
least squares mean (standard error)				
Month 15 (n=59,59,50)	72.74 (± 3.02)	87.22 (± 3.1)	87.67 (± 3.29)	
Month 18 (n=59,59,50)	73.56 (± 3.14)	87.52 (± 3.23)	87.12 (± 3.42)	
Month 24 (n=58,54,42)	72.7 (± 3.28)	87.72 (± 3.39)	87.62 (± 3.62)	
Month 30 (n=51,38,29)	70.7 (± 3.48)	89.24 (± 3.68)	87.15 (± 3.99)	
Month 36 (n=51,32,15)	70.71 (± 3.75)	85.91 (± 4.04)	85.64 (± 4.68)	
Month 42 (n=44,31,15)	69.63 (± 3.48)	85.95 (± 3.76)	81.88 (± 4.45)	
Month 48 (n=42,30,14)	67.63 (± 3.81)	83.96 (± 4.15)	77.42 (± 5.03)	
Month 54 (n=41,31,13)	65.81 (± 3.85)	82.78 (± 4.2)	77.6 (± 5.26)	
Month 60 (n=37,24,12)	70.52 (± 3.92)	78.54 (± 4.43)	74.18 (± 5.63)	
Month 66 (n=34,20,11)	69.09 (± 3.81)	79.09 (± 4.21)	74.52 (± 5.11)	
Month 72 (n=30,17,11)	68.34 (± 4.44)	85.5 (± 5.11)	73.05 (± 6.45)	

Statistical analyses

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault

Statistical analysis description:

Month 15

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[296]
P-value	= 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	14.48

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	10.83
upper limit	18.13
Variability estimate	Standard error of the mean
Dispersion value	4.33

Notes:
[296] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[297]
P-value	= 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	14.93
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	11.16
upper limit	18.7
Variability estimate	Standard error of the mean
Dispersion value	4.47

Notes:
[297] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[298]
P-value	= 0.0023
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	13.96
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	10.16
upper limit	17.76
Variability estimate	Standard error of the mean
Dispersion value	4.5

Notes:
[298] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[299]
P-value	= 0.0039
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	13.57
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	9.65
upper limit	17.48
Variability estimate	Standard error of the mean
Dispersion value	4.64

Notes:
[299] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[300]
P-value	= 0.0017
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	15.02
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	11.04
upper limit	19
Variability estimate	Standard error of the mean
Dispersion value	4.72

Notes:
[300] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[301]
P-value	= 0.0026
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	14.93
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	10.81
upper limit	19.04
Variability estimate	Standard error of the mean
Dispersion value	4.88

Notes:

[301] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[302]
P-value	= 0.0003
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	18.54
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	14.27
upper limit	22.81
Variability estimate	Standard error of the mean
Dispersion value	5.06

Notes:

[302] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[303]
P-value	= 0.0022
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	16.45

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	11.99
upper limit	20.91
Variability estimate	Standard error of the mean
Dispersion value	5.29

Notes:
[303] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[304]
P-value	= 0.0065
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	15.19
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	10.55
upper limit	19.84
Variability estimate	Standard error of the mean
Dispersion value	5.51

Notes:
[304] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[305]
P-value	= 0.0137
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	14.93
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	9.87
upper limit	19.99
Variability estimate	Standard error of the mean
Dispersion value	6

Notes:
[305] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[306]
P-value	= 0.0018
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	16.32
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	11.99
upper limit	20.64
Variability estimate	Standard error of the mean
Dispersion value	5.12

Notes:
[306] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[307]
P-value	= 0.0316
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	12.24
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	7.47
upper limit	17.01
Variability estimate	Standard error of the mean
Dispersion value	5.65

Notes:
[307] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[308]
P-value	= 0.0043
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	16.33
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	11.57
upper limit	21.09
Variability estimate	Standard error of the mean
Dispersion value	5.64

Notes:

[308] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[309]
P-value	= 0.1226
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	9.8
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	4.47
upper limit	15.12
Variability estimate	Standard error of the mean
Dispersion value	6.31

Notes:

[309] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[310]
P-value	= 0.0034
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	16.97

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	12.17
upper limit	21.78
Variability estimate	Standard error of the mean
Dispersion value	5.7

Notes:
[310] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[311]
P-value	= 0.0724
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	11.79
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	6.29
upper limit	17.29
Variability estimate	Standard error of the mean
Dispersion value	6.52

Notes:
[311] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[312]
P-value	= 0.1782
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	8.03
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	3.02
upper limit	13.03
Variability estimate	Standard error of the mean
Dispersion value	5.92

Notes:
[312] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[313]
P-value	= 0.5947
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	3.66
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-2.14
upper limit	9.46
Variability estimate	Standard error of the mean
Dispersion value	6.86

Notes:
[313] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[314]
P-value	= 0.081
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	9.99
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	5.2
upper limit	14.79
Variability estimate	Standard error of the mean
Dispersion value	5.68

Notes:
[314] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[315]
P-value	= 0.3965
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	5.42
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	0.04
upper limit	10.81
Variability estimate	Standard error of the mean
Dispersion value	6.38

Notes:
[315] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[316]
P-value	= 0.0128
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	17.16
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	11.44
upper limit	22.88
Variability estimate	Standard error of the mean
Dispersion value	6.77

Notes:
[316] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - Cockcroft-Gault
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[317]
P-value	= 0.5487
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	4.71

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	-1.91
upper limit	11.33
Variability estimate	Standard error of the mean
Dispersion value	7.83

Notes:

[317] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Secondary: LS Means of estimated GFR (eGFR) (mL/min/1.73m^2) Calculated by the Modification of Diet in Renal Disease (MDRD) Equation With Last Observation Carried Forward (LOCF) plus Imputation (eGFR=0 for graft loss/death) by Visit

End point title	LS Means of estimated GFR (eGFR) (mL/min/1.73m^2) Calculated by the Modification of Diet in Renal Disease (MDRD) Equation With Last Observation Carried Forward (LOCF) plus Imputation (eGFR=0 for graft loss/death) by Visit

End point description:

GFR: an index of kidney function. GFR described the flow rate of filtered fluid through the kidney. GFR was calculated using MDRD equation. GFR (mL/min/1.73 square meter (m^2) by MDRD equation = 170 * (serum creatinine [mg/dL])^(-0.999) * (age in years)^(-0.176) * (0.762 if female) * (1.18 if black) * (blood urea nitrogen concentration [mg/dL])^(-0.170) * (serum albumin concentration)^(0.318).A normal GFR is >90 mL/min/1.73 m^2, although children and older people usually have a lower GFR. Lower values indicated poor kidney function. A GFR <15 mL/min/1.73 m^2 indicated kidney failure. Model contained treatment, visit and treatment by visit interaction as fixed effects. An unstructured variance-covariance structure was used.

End point type	Secondary

End point timeframe:

Months 15, 18, 24, 30, 36, 42, 48, 54, 60, 66, 72

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: mL/min/1.73m^2				
least squares mean (standard error)				
Month 15	56.25 (± 1.99)	72.12 (± 2.06)	70.22 (± 2.17)	
Month 18	58.13 (± 2.32)	71.66 (± 2.39)	69.69 (± 2.52)	
Month 24	56.3 (± 2.4)	71.93 (± 2.47)	68.2 (± 2.61)	
Month 30	53.82 (± 2.69)	73.1 (± 2.78)	64.44 (± 2.93)	
Month 36	54.37 (± 3)	69.09 (± 3.1)	63.27 (± 3.26)	
Month 42	53.59 (± 2.96)	68.29 (± 3.05)	62.14 (± 3.22)	
Month 48	51.69 (± 3.23)	65.27 (± 3.34)	60.81 (± 3.52)	
Month 54	48.64 (± 3.29)	65.25 (± 3.4)	60.79 (± 3.59)	
Month 60	50.43 (± 3.3)	63.82 (± 3.41)	59.2 (± 3.59)	
Month 66	49.7 (± 3.34)	63.33 (± 3.45)	59.47 (± 3.63)	
Month 72	49.62 (± 3.51)	64.27 (± 3.62)	59.21 (± 3.82)	

Statistical analyses

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[318]
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	15.87
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	13.46
upper limit	18.29
Variability estimate	Standard error of the mean
Dispersion value	2.86

Notes:

[318] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 15	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[319]
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	13.97
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	11.49
upper limit	16.46
Variability estimate	Standard error of the mean
Dispersion value	2.95

Notes:

[319] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[320]
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	13.53
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	10.71
upper limit	16.34
Variability estimate	Standard error of the mean
Dispersion value	3.33

Notes:

[320] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 18	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[321]
P-value	= 0.0009
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	11.56
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	8.67
upper limit	14.45
Variability estimate	Standard error of the mean
Dispersion value	3.43

Notes:

[321] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[322]
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	15.63

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	12.72
upper limit	18.53
Variability estimate	Standard error of the mean
Dispersion value	3.44

Notes:
[322] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 24	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[323]
P-value	= 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	11.89
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	8.91
upper limit	14.88
Variability estimate	Standard error of the mean
Dispersion value	3.54

Notes:
[323] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[324]
P-value	< 0.0001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	19.29
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	16.03
upper limit	22.55
Variability estimate	Standard error of the mean
Dispersion value	3.86

Notes:
[324] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 30	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[325]
P-value	= 0.0082
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	10.63
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	7.27
upper limit	13.98
Variability estimate	Standard error of the mean
Dispersion value	3.97

Notes:
[325] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[326]
P-value	= 0.0008
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	14.72
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	11.09
upper limit	18.36
Variability estimate	Standard error of the mean
Dispersion value	4.31

Notes:
[326] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 36	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[327]
P-value	= 0.0462
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	8.9
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	5.16
upper limit	12.64
Variability estimate	Standard error of the mean
Dispersion value	4.43

Notes:

[327] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[328]
P-value	= 0.0007
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	14.7
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	11.11
upper limit	18.28
Variability estimate	Standard error of the mean
Dispersion value	4.25

Notes:

[328] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 42	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[329]
P-value	= 0.0519
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	8.55

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	4.87
upper limit	12.24
Variability estimate	Standard error of the mean
Dispersion value	4.37

Notes:
[329] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[330]
P-value	= 0.0039
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	13.58
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	9.66
upper limit	17.5
Variability estimate	Standard error of the mean
Dispersion value	4.65

Notes:
[330] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 48	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[331]
P-value	= 0.058
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	9.12
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	5.09
upper limit	13.15
Variability estimate	Standard error of the mean
Dispersion value	4.78

Notes:
[331] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[332]
P-value	= 0.0006
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	16.61
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	12.62
upper limit	20.61
Variability estimate	Standard error of the mean
Dispersion value	4.74

Notes:
[332] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 54	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[333]
P-value	= 0.0136
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	12.15
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	8.04
upper limit	16.26
Variability estimate	Standard error of the mean
Dispersion value	4.87

Notes:
[333] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[334]
P-value	= 0.0053
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	13.39
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	9.39
upper limit	17.39
Variability estimate	Standard error of the mean
Dispersion value	4.74

Notes:

[334] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 60	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[335]
P-value	= 0.0736
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	8.77
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	4.66
upper limit	12.88
Variability estimate	Standard error of the mean
Dispersion value	4.87

Notes:

[335] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[336]
P-value	= 0.005
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	13.63

Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	9.58
upper limit	17.67
Variability estimate	Standard error of the mean
Dispersion value	4.8

Notes:
[336] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 66	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[337]
P-value	= 0.0491
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	9.77
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	5.61
upper limit	13.93
Variability estimate	Standard error of the mean
Dispersion value	4.93

Notes:
[337] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[338]
P-value	= 0.0041
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	14.66
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	10.4
upper limit	18.91
Variability estimate	Standard error of the mean
Dispersion value	5.04

Notes:
[338] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of Estimated GFR - MDRD Equation (LOCF)
Statistical analysis description:	
Month 72	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[339]
P-value	= 0.066
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	9.59
Confidence interval	
level	Other: 60 %
sides	2-sided
lower limit	5.22
upper limit	13.97
Variability estimate	Standard error of the mean
Dispersion value	5.19

Notes:
[339] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Secondary: LS Means of Short Form 36 Version 2 (SF-36 V2) Component and Domain Scores at Months 24 and 36

End point title	LS Means of Short Form 36 Version 2 (SF-36 V2) Component and Domain Scores at Months 24 and 36

End point description:

The SF-36v2 is a self administered, 36-item generic health status measure. It measures 8 general health concepts: Physical Functioning, Role Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role Emotional, and Mental Health. These concepts were also summarized into 2 summary scores, the Physical Component Summary and Mental Component Summary. Higher domain and summary scores indicate better health status. The 8 subscales, 2 composite subscales and Question 2 of the Questionnaire were subjected to analysis. Model contained treatment, visit and treatment by visit interaction as fixed effects and Baseline (predose in Study A3921030) as a covariate. A first-order autoregressive variance-covariance structure was used.

End point type	Secondary

End point timeframe:

Months 24, 36

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: Score on a scale				
least squares mean (standard error)				
Month 24 (n=41,33,24): Physical Functioning	49.04 (± 1.16)	47 (± 1.29)	45.47 (± 1.49)	
Month 24 (n=41,33,24): Role Physical	46.36 (± 1.41)	47.72 (± 1.56)	44.4 (± 1.82)	

Month 24 (n=41,33,24): Bodily Pain	51.37 (± 1.42)	51.66 (± 1.58)	51.47 (± 1.84)	
Month 24 (n=41,33,24): General Health	46.51 (± 1.19)	48.25 (± 1.32)	47.6 (± 1.54)	
Month 24 (n=41,33,24): Vitality	53.31 (± 1.25)	53.27 (± 1.39)	55.07 (± 1.64)	
Month 24 (n=41,33,24): Social Functioning	49.55 (± 1.33)	49.41 (± 1.47)	49.95 (± 1.74)	
Month 24 (n=41,33,24): Role Emotional	44.65 (± 1.55)	48.47 (± 1.72)	44.17 (± 2.01)	
Month 24 (n=41,33,24): Mental Health	49.52 (± 1.35)	47.83 (± 1.5)	53.08 (± 1.76)	
Month 24 (n=41,33,24): TR Scale Score	2.63 (± 0.1)	2.85 (± 0.12)	2.86 (± 0.14)	
Month 24 (n=41,33,24): Physical Component Summary	49 (± 1.13)	48.99 (± 1.25)	46.57 (± 1.45)	
Month 24 (n=41,33,24): Mental Component Summary	48.65 (± 1.29)	49.62 (± 1.43)	51.92 (± 1.68)	
Month 36 (n=35,21,10): Physical Functioning	48.62 (± 1.25)	46.97 (± 1.6)	46.18 (± 2.27)	
Month 36 (n=35,21,10): Role Physical	48 (± 1.52)	48.52 (± 1.94)	46 (± 2.79)	
Month 36 (n=35,21,10): Bodily Pain	50.57 (± 1.54)	52.66 (± 1.97)	50.19 (± 2.84)	
Month 36 (n=35,21,10): General Health	46.06 (± 1.29)	47.83 (± 1.63)	47.02 (± 2.32)	
Month 36 (n=35,21,10): Vitality	53.01 (± 1.35)	54.45 (± 1.73)	57.43 (± 2.5)	
Month 36 (n=35,21,10): Social Functioning	48.96 (± 1.44)	51.43 (± 1.84)	48.33 (± 2.65)	
Month 36 (n=35,21,10): Role Emotional	46.35 (± 1.68)	51.97 (± 2.15)	47.58 (± 3.09)	
Month 36 (n=35,21,10): Mental health	50.21 (± 1.46)	51.84 (± 1.86)	50.59 (± 2.68)	
Month 36 (n=35,21,10): TR Scale Score	2.46 (± 0.11)	2.65 (± 0.14)	2.83 (± 0.21)	
Month 36 (n=35,21,10): Physical Component Summary	48.55 (± 1.22)	48 (± 1.55)	47.07 (± 2.21)	
Month 36 (n=35,21,10): Mental Component Summary	49.45 (± 1.39)	53.5 (± 1.77)	52.32 (± 2.55)	

Statistical analyses

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description: Month 24: Physical Functioning	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[340]
P-value	= 0.2393
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.45
upper limit	1.36
Variability estimate	Standard error of the mean
Dispersion value	1.73

Notes:

[340] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 24: Physical Functioning	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[341]
P-value	= 0.0595
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-3.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.29
upper limit	0.14
Variability estimate	Standard error of the mean
Dispersion value	1.89

Notes:

[341] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 24: Role Physical	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[342]
P-value	= 0.5182
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.77
upper limit	5.49
Variability estimate	Standard error of the mean
Dispersion value	2.1

Notes:

[342] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 24: Role Physical	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[343]
P-value	= 0.3938
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.49
upper limit	2.56
Variability estimate	Standard error of the mean
Dispersion value	2.3

Notes:

[343] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 24: Bodily Pain	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[344]
P-value	= 0.8932
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.89
upper limit	4.46
Variability estimate	Standard error of the mean
Dispersion value	2.12

Notes:

[344] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 24: Bodily Pain	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[345]
P-value	= 0.9673
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.1

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.48
upper limit	4.67
Variability estimate	Standard error of the mean
Dispersion value	2.33

Notes:
[345] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description: Month 24: General Health	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[346]
P-value	= 0.329
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.76
upper limit	5.23
Variability estimate	Standard error of the mean
Dispersion value	1.78

Notes:
[346] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description: Month 24: General Health	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[347]
P-value	= 0.578
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.75
upper limit	4.92
Variability estimate	Standard error of the mean
Dispersion value	1.95

Notes:
[347] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF36 V2 Component and Domain Scores
Statistical analysis description:	
Month 24: Vitality	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[348]
P-value	= 0.9799
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.72
upper limit	3.62
Variability estimate	Standard error of the mean
Dispersion value	1.87

Notes:
[348] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 24: Vitality	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[349]
P-value	= 0.396
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.31
upper limit	5.83
Variability estimate	Standard error of the mean
Dispersion value	2.07

Notes:
[349] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 24: Social Functioning	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[350]
P-value	= 0.94
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.05
upper limit	3.75
Variability estimate	Standard error of the mean
Dispersion value	1.98

Notes:

[350] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 24: Social Functioning	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[351]
P-value	= 0.8583
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.94
upper limit	4.72
Variability estimate	Standard error of the mean
Dispersion value	2.2

Notes:

[351] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 24: Role Emotional	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[352]
P-value	= 0.0997
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	3.82

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.73
upper limit	8.37
Variability estimate	Standard error of the mean
Dispersion value	2.31

Notes:
[352] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description: Month 24: Role Emotional	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[353]
P-value	= 0.852
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.47
upper limit	4.52
Variability estimate	Standard error of the mean
Dispersion value	2.54

Notes:
[353] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description: Month 24: Mental Health	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[354]
P-value	= 0.4023
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.64
upper limit	2.27
Variability estimate	Standard error of the mean
Dispersion value	2.01

Notes:
[354] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 24: Mental Health	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[355]
P-value	= 0.1092
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	3.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.8
upper limit	7.92
Variability estimate	Standard error of the mean
Dispersion value	2.22

Notes:
[355] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 24: TR Scale Score	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[356]
P-value	= 0.1754
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	0.52
Variability estimate	Standard error of the mean
Dispersion value	0.16

Notes:
[356] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 24: TR Scale Score	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[357]
P-value	= 0.1802
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.11
upper limit	0.57
Variability estimate	Standard error of the mean
Dispersion value	0.17

Notes:

[357] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores

Statistical analysis description:

Month 24: Physical Component Summary

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[358]
P-value	= 0.9966
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.31
upper limit	3.29
Variability estimate	Standard error of the mean
Dispersion value	1.68

Notes:

[358] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS means of SF-36 V2 Component and Domain Scores

Statistical analysis description:

Month 24: Physical Component Summary

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[359]
P-value	= 0.188
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2.42

Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.04
upper limit	1.19
Variability estimate	Standard error of the mean
Dispersion value	1.84

Notes:
[359] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 24: Mental Component Summary	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[360]
P-value	= 0.6154
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.81
upper limit	4.73
Variability estimate	Standard error of the mean
Dispersion value	1.92

Notes:
[360] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 24: Mental Component Summary	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[361]
P-value	= 0.1248
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	3.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.91
upper limit	7.43
Variability estimate	Standard error of the mean
Dispersion value	2.12

Notes:
[361] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: Physical Functioning	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[362]
P-value	= 0.4174
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.63
upper limit	2.34
Variability estimate	Standard error of the mean
Dispersion value	2.03

Notes:
[362] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: Physical Functioning	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[363]
P-value	= 0.3486
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.54
upper limit	2.66
Variability estimate	Standard error of the mean
Dispersion value	2.6

Notes:
[363] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: Role Physical	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[364]
P-value	= 0.8335
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.33
upper limit	5.37
Variability estimate	Standard error of the mean
Dispersion value	2.47

Notes:

[364] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: Role Physical	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[365]
P-value	= 0.5291
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.24
upper limit	4.24
Variability estimate	Standard error of the mean
Dispersion value	3.18

Notes:

[365] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: Bodily Pain	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[366]
P-value	= 0.4033
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.09

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.82
upper limit	7
Variability estimate	Standard error of the mean
Dispersion value	2.5

Notes:
[366] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description: Month 36: Bodily Pain	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[367]
P-value	= 0.9078
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.74
upper limit	5.99
Variability estimate	Standard error of the mean
Dispersion value	3.24

Notes:
[367] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description: Month 36: General Health	
Comparison groups	Tofacitinib Less Intensive (LI) v Cyclosporine (CsA)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[368]
P-value	= 0.3947
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.31
upper limit	5.86
Variability estimate	Standard error of the mean
Dispersion value	2.08

Notes:
[368] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: General Health	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[369]
P-value	= 0.7165
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.26
upper limit	6.2
Variability estimate	Standard error of the mean
Dispersion value	2.66

Notes:
[369] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: Vitality	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[370]
P-value	= 0.5112
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.87
upper limit	5.75
Variability estimate	Standard error of the mean
Dispersion value	2.19

Notes:
[370] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: Vitality	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[371]
P-value	= 0.1218
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	4.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.18
upper limit	10.04
Variability estimate	Standard error of the mean
Dispersion value	2.86

Notes:

[371] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: Social Functioning	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[372]
P-value	= 0.2895
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.11
upper limit	7.05
Variability estimate	Standard error of the mean
Dispersion value	2.33

Notes:

[372] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: Social Functioning	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[373]
P-value	= 0.8349
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.63

Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.58
upper limit	5.32
Variability estimate	Standard error of the mean
Dispersion value	3.03

Notes:
[373] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description: Month 36: Role Emotional	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[374]
P-value	= 0.0393
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	5.62
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.28
upper limit	10.97
Variability estimate	Standard error of the mean
Dispersion value	2.72

Notes:
[374] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description: Month 36: Role Emotional	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[375]
P-value	= 0.7266
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.69
upper limit	8.16
Variability estimate	Standard error of the mean
Dispersion value	3.52

Notes:
[375] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: Mental Health	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[376]
P-value	= 0.4916
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.02
upper limit	6.27
Variability estimate	Standard error of the mean
Dispersion value	2.36

Notes:
[376] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: Mental Health	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[377]
P-value	= 0.9008
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.62
upper limit	6.38
Variability estimate	Standard error of the mean
Dispersion value	3.05

Notes:
[377] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: TR Scale Score	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[378]
P-value	= 0.2965
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.17
upper limit	0.55
Variability estimate	Standard error of the mean
Dispersion value	0.18

Notes:

[378] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: TR Scale Score	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[379]
P-value	= 0.1147
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.37
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.09
upper limit	0.84
Variability estimate	Standard error of the mean
Dispersion value	0.24

Notes:

[379] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: Physical Component Summary	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[380]
P-value	= 0.7786
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.55

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.42
upper limit	3.31
Variability estimate	Standard error of the mean
Dispersion value	1.97

Notes:
[380] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: Physical Component Summary	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[381]
P-value	= 0.5582
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.45
upper limit	3.49
Variability estimate	Standard error of the mean
Dispersion value	2.53

Notes:
[381] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: Mental Component Summary	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[382]
P-value	= 0.0727
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	4.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.37
upper limit	8.47
Variability estimate	Standard error of the mean
Dispersion value	2.25

Notes:
[382] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SF-36 V2 Component and Domain Scores
Statistical analysis description:	
Month 36: Mental Component Summary	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[383]
P-value	= 0.3264
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	2.86
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.86
upper limit	8.59
Variability estimate	Standard error of the mean
Dispersion value	2.91

Notes:
[383] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Secondary: LS Means of End-Stage Renal Disease (ESRD) Symptom Checklist (SCL) - Transplantation Modules at Months 24 and 36

End point title	LS Means of End-Stage Renal Disease (ESRD) Symptom Checklist (SCL) -Transplantation Modules at Months 24 and 36

End point description:

ESRD-SCL: a 43-item disease specific self-administered questionnaire. Participants' rated the question "At the moment,how much do you suffer?" for each item on a 5 point scale, range (Ra) from 0 (not at all) to 4 (extremely). Consisted of 6 subscales: Cardiac and Renal (CR) dysfunction; Ra 0 to 28, Increased(In) Growth of Gum and Hair (IGGH); Ra 0 to 20, Limited Cognitive Capacity (LCC); Ra 0 to 32, Limited Physical Capacity (LPC); Ra 0 to 40, Side Effects (SEs) of Corticosteroids; Ra 0 to 20, Transplantation Associated Psychological Distress (TAPD); Ra 0 to 32. Total Score: 0 to 172, higher scores indicate greater dysfunction. Model contained treatment, visit and treatment by visit interaction as fixed effects and Baseline (predose in Study A3921030) as a covariate. A first-order autoregressive variance-covariance structure was used.

End point type	Secondary

End point timeframe:

Months 24, 36

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: Score on a scale				
least squares mean (standard error)				
Month 24 Limited Physical Capacity (n=40,33,23)	0.59 (± 0.07)	0.7 (± 0.08)	0.71 (± 0.1)	

Month 24 Limited Cognitive Capacity (n=40,34,23)	0.63 (± 0.08)	0.71 (± 0.08)	0.75 (± 0.1)	
Month 24 CR Dysfunction (n=40,33,23)	0.63 (± 0.07)	0.58 (± 0.08)	0.53 (± 0.1)	
Month 24 SE of Corticosteroids (40, 33, 23)	0.42 (± 0.08)	0.57 (± 0.09)	0.6 (± 0.11)	
Month 24 IGGH (n=40,33,23)	0.54 (± 0.07)	0.19 (± 0.08)	0.17 (± 0.09)	
Month 24 TAPD (n=40,34,23)	0.61 (± 0.08)	0.77 (± 0.09)	0.63 (± 0.11)	
Month 24 Global Score (n=40,33,23)	0.58 (± 0.06)	0.62 (± 0.06)	0.59 (± 0.07)	
Month 36 Limited Physical Capacity (n=33,21,8)	0.71 (± 0.08)	0.69 (± 0.1)	0.88 (± 0.16)	
Month 36 Limited Cognitive Capacity (n=34,21,8)	0.67 (± 0.08)	0.73 (± 0.1)	0.85 (± 0.17)	
Month 36 Cardiac and Renal Dysfunction (n=33,21,8)	0.58 (± 0.08)	0.57 (± 0.1)	0.76 (± 0.16)	
Month 36 SE of Corticosteroids (n=33,21,8)	0.44 (± 0.09)	0.39 (± 0.11)	0.58 (± 0.18)	
Month 36 IGGH (n=33,20,8)	0.54 (± 0.08)	0.33 (± 0.1)	0.23 (± 0.15)	
Month 36 TAPD (n=34,21,8)	0.77 (± 0.09)	0.82 (± 0.11)	0.68 (± 0.18)	
Month 36 Global Score (n=33,21,8)	0.64 (± 0.06)	0.63 (± 0.08)	0.7 (± 0.12)	

Statistical analyses

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description:	
Month 24 Limited Physical Capacity	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[384]
P-value	= 0.3093
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.1
upper limit	0.33
Variability estimate	Standard error of the mean
Dispersion value	0.11

Notes:

[384] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description:	
Month 24 Limited Physical Capacity	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[385]
P-value	= 0.3223
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.12
upper limit	0.36
Variability estimate	Standard error of the mean
Dispersion value	0.12

Notes:

[385] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description:	
Month 24 Limited Cognitive Capacity	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[386]
P-value	= 0.4858
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.08
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.14
upper limit	0.3
Variability estimate	Standard error of the mean
Dispersion value	0.11

Notes:

[386] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description:	
Month 24 Limited Cognitive Capacity	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[387]
P-value	= 0.3679
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.11

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.13
upper limit	0.36
Variability estimate	Standard error of the mean
Dispersion value	0.13

Notes:
[387] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description: Month 24 Cardiac and Renal Dysfunction	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[388]
P-value	= 0.6416
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.27
upper limit	0.17
Variability estimate	Standard error of the mean
Dispersion value	0.11

Notes:
[388] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description: Month 24 Cardiac and Renal Dysfunction	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[389]
P-value	= 0.4241
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.34
upper limit	0.14
Variability estimate	Standard error of the mean
Dispersion value	0.12

Notes:
[389] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description:	
Month 24 Side Effects of Corticosteroids	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[390]
P-value	= 0.2133
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.09
upper limit	0.39
Variability estimate	Standard error of the mean
Dispersion value	0.12

Notes:
[390] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description:	
Month 24 Side Effects of Corticosteroids	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[391]
P-value	= 0.1918
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.09
upper limit	0.44
Variability estimate	Standard error of the mean
Dispersion value	0.13

Notes:
[391] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description:	
Month 24 Increased Growth of Gum and Hair	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[392]
P-value	= 0.001
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.55
upper limit	-0.14
Variability estimate	Standard error of the mean
Dispersion value	0.1

Notes:

[392] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules

Statistical analysis description:

Month 24 Increased Growth of Gum and Hair

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[393]
P-value	= 0.002
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.59
upper limit	-0.13
Variability estimate	Standard error of the mean
Dispersion value	0.12

Notes:

[393] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules

Statistical analysis description:

Month 24 Transplantation-Associated Psychological Distress

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[394]
P-value	= 0.2012
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.16

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.08
upper limit	0.4
Variability estimate	Standard error of the mean
Dispersion value	0.12

Notes:
[394] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description:	
Month 24 Transplantation-Associated Psychological Distress	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[395]
P-value	= 0.8986
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.25
upper limit	0.29
Variability estimate	Standard error of the mean
Dispersion value	0.14

Notes:
[395] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description:	
Month 24 Global Score	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[396]
P-value	= 0.6724
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.13
upper limit	0.2
Variability estimate	Standard error of the mean
Dispersion value	0.08

Notes:
[396] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description: Month 24 Global Score	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[397]
P-value	= 0.9297
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.18
upper limit	0.19
Variability estimate	Standard error of the mean
Dispersion value	0.09

Notes:
[397] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description: Month 36 Limited Physical Capacity	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[398]
P-value	= 0.8682
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.28
upper limit	0.23
Variability estimate	Standard error of the mean
Dispersion value	0.13

Notes:
[398] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description: Month 36 Limited Physical Capacity	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[399]
P-value	= 0.3392
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.18
upper limit	0.53
Variability estimate	Standard error of the mean
Dispersion value	0.18

Notes:

[399] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description:	
Month 36 Limited Cognitive Capacity	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[400]
P-value	= 0.6545
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.32
Variability estimate	Standard error of the mean
Dispersion value	0.13

Notes:

[400] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description:	
Month 36 Limited Cognitive Capacity	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[401]
P-value	= 0.3253
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.18

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.18
upper limit	0.55
Variability estimate	Standard error of the mean
Dispersion value	0.19

Notes:
[401] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS means of ESRD SCL Transplantation Modules
Statistical analysis description: Month 36 Cardiac and Renal Dysfunction	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[402]
P-value	= 0.9698
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.26
upper limit	0.25
Variability estimate	Standard error of the mean
Dispersion value	0.13

Notes:
[402] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description: Month 36 Cardiac and Renal Dysfunction	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[403]
P-value	= 0.3065
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.17
upper limit	0.54
Variability estimate	Standard error of the mean
Dispersion value	0.18

Notes:
[403] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS means of ESRD SCL Transplantation Modules
Statistical analysis description:	
Month 36 Side Effects of Corticosteroids	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[404]
P-value	= 0.7147
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.33
upper limit	0.23
Variability estimate	Standard error of the mean
Dispersion value	0.14

Notes:
[404] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description:	
Month 36 Side Effects of Corticosteroids	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[405]
P-value	= 0.4852
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.25
upper limit	0.53
Variability estimate	Standard error of the mean
Dispersion value	0.2

Notes:
[405] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description:	
Month 36 Increased Growth of Gum and Hair	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)

Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[406]
P-value	= 0.0888
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.46
upper limit	0.03
Variability estimate	Standard error of the mean
Dispersion value	0.13

Notes:

[406] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules

Statistical analysis description:

Month 36 Increased Growth of Gum and Hair

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[407]
P-value	= 0.0719
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.65
upper limit	0.03
Variability estimate	Standard error of the mean
Dispersion value	0.17

Notes:

[407] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules

Statistical analysis description:

Month 36 Transplantation-Associated Psychological Distress

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[408]
P-value	= 0.7531
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.05

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.24
upper limit	0.33
Variability estimate	Standard error of the mean
Dispersion value	0.14

Notes:
[408] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description:	
Month 36 Transplantation-Associated Psychological Distress	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[409]
P-value	= 0.6412
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.49
upper limit	0.3
Variability estimate	Standard error of the mean
Dispersion value	0.2

Notes:
[409] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description:	
Month 36 Global Score	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[410]
P-value	= 0.9186
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.2
upper limit	0.18
Variability estimate	Standard error of the mean
Dispersion value	0.1

Notes:
[410] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of ESRD SCL Transplantation Modules
Statistical analysis description: Month 36 Global Score	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[411]
P-value	= 0.6629
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.21
upper limit	0.33
Variability estimate	Standard error of the mean
Dispersion value	0.14

Notes:
[411] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Secondary: LSMeans of Severity of Dyspepsia Assessment (SODA) Subscales at Months 24 & 36

End point title	LSMeans of Severity of Dyspepsia Assessment (SODA) Subscales at Months 24 & 36

End point description:

SODA:17-item health scale, assessed participant-reported perceptions of dyspepsia; consists of 3 subscales: Pain Intensity (PI, 6-items to assess pain and intensity of abdominal discomfort; Range: 2 to 47, higher score indicates greater pain and abdominal discomfort), Non-Pain Symptoms (NPS, 7-items to assess severity and impact of non-pain symptoms: burping/belching, heartburn, bloating, flatulence, sour taste, nausea, and bad breath; Range: 7 to 35, higher scores indicate increased symptom severity and influence), and Satisfaction (4-items to assess degree of satisfaction with abdominal discomfort; Range: 2 to 23, higher scores indicate more satisfaction). Model contained treatment, visit and treatment by visit interaction as fixed effects and Baseline (predose in Study A3921030) as a covariate. A first-order autoregressive variance-covariance structure was used.

End point type	Secondary

End point timeframe:
Months 24, 36

End point values	Cyclosporine (CsA)	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	60	54	
Units: Score				
least squares mean (standard error)				
Month 24 PI Total Converted Score (n=46,39,24)	9.51 (± 1.16)	7.66 (± 1.26)	10.73 (± 1.59)	

Month 24 NPS Converted Score (n=49,41,25)	11.44 (± 0.42)	11.24 (± 0.46)	12.25 (± 0.58)	
Month 24 Satisfaction Converted Score (n=49,41,24)	17.22 (± 0.66)	18.11 (± 0.72)	16.33 (± 0.94)	
Month 36 PI Total Converted Score (n=40,27,10)	9.63 (± 1.25)	8.03 (± 1.51)	10.59 (± 2.45)	
Month 36 NPS Converted Score (n=42,28,10)	11.31 (± 0.45)	11.14 (± 0.55)	12.44 (± 0.91)	
Month 36 Satisfaction Converted Score (n=42,28,10)	17.44 (± 0.72)	17.9 (± 0.87)	16.31 (± 1.45)	

Statistical analyses

Statistical analysis title	LS Means of SODA Subscales
Statistical analysis description:	
Month 24 Pain Intensity Total Converted Score	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[412]
P-value	= 0.2826
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.22
upper limit	1.53
Variability estimate	Standard error of the mean
Dispersion value	1.72

Notes:

[412] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SODA Subscales
Statistical analysis description:	
Month 24 Pain Intensity Total Converted Score	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[413]
P-value	= 0.5371
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.65
upper limit	5.09

Variability estimate	Standard error of the mean
Dispersion value	1.97

Notes:
[413] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SODA Subscales

Statistical analysis description:
Month 24 Non-Pain Symptoms Converted Score

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[414]
P-value	= 0.7503
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.41
upper limit	1.02
Variability estimate	Standard error of the mean
Dispersion value	0.62

Notes:
[414] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SODA Subscales

Statistical analysis description:
Month 24 Non-Pain Symptoms Converted Score

Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[415]
P-value	= 0.261
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.6
upper limit	2.21
Variability estimate	Standard error of the mean
Dispersion value	0.72

Notes:
[415] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SODA Subscales

Statistical analysis description:
Month 24 Satisfaction Converted Score

Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[416]
P-value	= 0.3656
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.04
upper limit	2.82
Variability estimate	Standard error of the mean
Dispersion value	0.98

Notes:

[416] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SODA Subscales
Statistical analysis description:	
Month 24 Satisfaction Converted Score	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[417]
P-value	= 0.4405
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.16
upper limit	1.37
Variability estimate	Standard error of the mean
Dispersion value	1.15

Notes:

[417] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SODA Subscales
Statistical analysis description:	
Month 36 Pain Intensity Total Converted Score	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[418]
P-value	= 0.4135
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.45
upper limit	2.25
Variability estimate	Standard error of the mean
Dispersion value	1.96

Notes:
[418] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SODA Subscales
Statistical analysis description:	
Month 36 Pain Intensity Total Converted Score	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[419]
P-value	= 0.7272
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.45
upper limit	6.37
Variability estimate	Standard error of the mean
Dispersion value	2.75

Notes:
[419] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SODA Subscales
Statistical analysis description:	
Month 36 Non-Pain symptoms Converted Score	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[420]
P-value	= 0.8111
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.56
upper limit	1.22
Variability estimate	Standard error of the mean
Dispersion value	0.71

Notes:
[420] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SODA Subscales
Statistical analysis description:	
Month 36 Non-Pain Symptoms Converted Score	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[421]
P-value	= 0.2636
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	1.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.86
upper limit	3.13
Variability estimate	Standard error of the mean
Dispersion value	1.02

Notes:
[421] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SODA Subscales
Statistical analysis description:	
Month 36 Satisfaction Converted Score	
Comparison groups	Cyclosporine (CsA) v Tofacitinib Less Intensive (LI)
Number of subjects included in analysis	124
Analysis specification	Pre-specified
Analysis type	superiority[422]
P-value	= 0.689
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	0.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.77
upper limit	2.67
Variability estimate	Standard error of the mean
Dispersion value	1.13

Notes:
[422] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Statistical analysis title	LS Means of SODA Subscales
Statistical analysis description:	
Month 36 Satisfaction Converted Score	
Comparison groups	Cyclosporine (CsA) v Tofacitinib More Intensive (MI)

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	superiority[423]
P-value	= 0.4853
Method	Mixed models analysis
Parameter estimate	Mean difference (final values)
Point estimate	-1.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.31
upper limit	2.05
Variability estimate	Standard error of the mean
Dispersion value	1.62

Notes:

[423] - 'Standard error of the mean' refers to 'standard error of the mean difference'

Secondary: Mean Trough Levels of Tofacitinib by Visit

End point title	Mean Trough Levels of Tofacitinib by Visit[424]

End point description:

The dates and times were recorded for the 6 doses of tofacitinib administered before each scheduled PK sampling. The participant was instructed to follow a 12 hourly schedule for these 6 doses of tofacitinib, with each dose administered within 1 hour of the scheduled time. Trough samples were collected 0 to 10 minutes prior to the morning dose. 1 hour postdose samples were required within 10 minutes of the nominal time point. Samples taken at -2 hours predose and at time points >1 hour post dose were required within 30 minutes of the nominal time point.

End point type	Secondary

End point timeframe:

Months 18 and 24 (-2 hours, predose, 1 hour, 2 hours), Month 30 (predose, 1 hour and 2 hours), Month 36 (predose, 1, 2, and 4 hours), Months 42, 48, 54, 60, 66, 72 (predose and 2 hours)

Notes:

[424] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was defined for comparator and tofacitinb separately in the Sponsor agreed Endpoints list because the treatment groups had PK measures reported at different timepoints. All treatment groups in the baseline period arms are reported, but across 2 separate endpoints

End point values	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60	54		
Units: ng/mL				
arithmetic mean (standard deviation)				
Month 18 Predose -2 hours (n=31,22)	13.2 (± 10.43)	10.68 (± 6.86)		
Month 18 Predose (n=58,46)	12.45 (± 11.83)	15.27 (± 24.14)		
Month 18 1 hour (n=58,45)	56.62 (± 32.96)	56.58 (± 37.56)		
Month 18 2 hours (n=26,23)	59.55 (± 25.87)	56.6 (± 28.85)		
Month 24 Predose -2 hours (n=18,15)	11.71 (± 11.77)	8.95 (± 8.72)		
Month 24 Predose (n=50,32)	9.93 (± 14.5)	7.42 (± 4.88)		

Month 24 1 hour (n=49,31)	44.06 (± 26.16)	41.93 (± 27.27)		
Month 24 2 hours (n=28,15)	37.73 (± 14)	34.15 (± 15.27)		
Month 30 Predose (n=35,21)	8.7 (± 8.53)	6.89 (± 6.94)		
Month 30 1 hour (n=35,21)	39.15 (± 16.06)	44.12 (± 19.99)		
Month 30 2 hours (n=34,19)	38.07 (± 11.42)	37.16 (± 17.51)		
Month 36 Predose (n=31,15)	6.35 (± 4.68)	8.33 (± 10.76)		
Month 36 1 hour (n=30,14)	46.09 (± 12.54)	38.07 (± 14.06)		
Month 36 2 hours (n=30,15)	38.11 (± 14.41)	31.76 (± 7.45)		
Month 36 4 hours (n=30,15)	24.03 (± 10.34)	21.46 (± 4.33)		
Month 42 Predose (n=31,14)	11.42 (± 12.07)	7 (± 5.34)		
Month 42 2 hours (n=30,12)	35.27 (± 15.57)	34.33 (± 11.1)		
Month 48 Predose (n=32,14)	7.58 (± 6.94)	13.78 (± 11.05)		
Month 48 2 hours (n=32,12)	38.46 (± 12.36)	41.1 (± 12.35)		
Month 54 Predose (n=30,11)	7.86 (± 5.52)	7.09 (± 6.45)		
Month 54 2 hours (n=30,10)	41.18 (± 12.25)	48.03 (± 10.39)		
Month 60 Predose (n=23,10)	6.58 (± 3.82)	7.31 (± 5.41)		
Month 60 2 hours (n=23,10)	39.43 (± 9.26)	38.98 (± 13.33)		
Month 66 Predose (n=22,10)	7.53 (± 9.19)	5.81 (± 6.03)		
Month 66 2 hours (n=21,10)	36.17 (± 12.74)	41.12 (± 12.27)		
Month 72 Predose (n=16,8)	8.3 (± 7.22)	5.37 (± 5.05)		
Month 72 2 hours (n=16,8)	38.55 (± 14.38)	38.93 (± 13.19)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Trough Levels of Cyclosporine by Visit

End point title	Mean Trough Levels of Cyclosporine by Visit[425]

End point description:

All CsA samples were taken predose (collected 0 to 10 minutes prior to the morning dose).

End point type	Secondary

End point timeframe:

Predose: Months 18, 24, 36, 48, 60, 72

Notes:

[425] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was defined for comparator and tofacitinb separately in the Sponsor agreed Endpoints list because the treatment groups had PK measures reported at different timepoints. All treatment groups in the baseline period arms are reported, but across 2 separate endpoints

End point values	Cyclosporine (CsA)			
Subject group type	Reporting group			
Number of subjects analysed	64			
Units: ng/mL				
arithmetic mean (standard deviation)				
Month 18 (n=58)	113.88 (± 98.73)			
Month 24 (n=54)	89.52 (± 45.23)			
Month 36 (n=50)	101.1 (± 100.63)			
Month 48 (n=39)	88.54 (± 62.45)			
Month 60 (n=35)	95 (± 115.74)			
Month 72 (n=23)	135.3 (± 188.05)			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Adverse events recorded from the time the participant took at least one dose of study treatment through last participant visit. Serious adverse events were recorded from informed consent through and including 28 calendar days from last administration.

Adverse event reporting additional description:

The same event may appear as both an AE and SAE. An event may be categorized as serious in 1 participant and non-serious in another, or 1 participant may have experienced both a serious and non-serious event during the study. The total number of deaths from AEs represents deaths from SAEs considered by the investigator as related to treatment.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.0

Reporting groups

Reporting group title	Cyclosporine

Reporting group description:

CsA was administered for up to 60 months as CsA microemulsion (Neoral® brand in the United States) orally twice daily (BID) in 2 equal doses approximately 12 hours apart. The dosage was adjusted to achieve a 12 hour trough whole blood level of approximately 75 to 200 nanograms per milliliter (ng/mL). Participants also received oral mycophenolate mofetil (MMF) 1 to 2 gram tablet daily throughout this extension study (or up to 3 mg daily for Black participants). Prednisone 5mg daily (or equivalent) was also maintained through at least 12 months posttransplant (parent study).

Reporting group title	Tofacitinib Less Intensive (LI)

Reporting group description:

Tofacitinib was administered for up to 60 months. During the parent study (A3921030), participants received 15 milligram (mg) tablet orally BID for Months 1 to 3 posttransplant then 10 mg tablet orally BID from Month 4. On entry to this extension study (Month 12), the dose was continued and tapered to 5 mg BID as early as Month 12 and by Month 18 posttransplant. Total tofacitinib LI treatment was up to 72 months posttransplant (12 months parent study and 60 months extension). Participants also received oral MMF 1 to 2 gram tablet daily throughout this extension study. Prednisone 5mg daily (or equivalent) was also maintained through at least 12 months posttransplant (parent study).

Reporting group title	Tofacitinib More Intensive (MI)

Reporting group description:

Tofacitinib was administered for up to 60 months. During the parent study (A3921030), participants received 15 mg tablet orally BID for Months 1 to 6 posttransplant then 10 mg tablet orally BID from Month 7. On entry to this extension study (Month 12), the dose was continued and tapered to 5 mg BID as early as Month 12 and by Month 18 posttransplant. Total tofacitinib MI treatment was up to 72 months posttransplant (12 months parent study and 60 months extension). Participants also received oral MMF 1 to 2 gram tablet daily throughout this extension study. Prednisone 5mg daily (or equivalent) was also maintained through at least 12 months posttransplant (parent study).

Serious adverse events	Cyclosporine	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)
Total subjects affected by serious adverse events			
subjects affected / exposed	40 / 64 (62.50%)	32 / 60 (53.33%)	31 / 54 (57.41%)
number of deaths (all causes)	4	1	5
number of deaths resulting from adverse events	2	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Basal cell carcinoma			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix carcinoma stage 0			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangiocarcinoma			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Clear cell renal cell carcinoma			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoma			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to peritoneum			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Neuroendocrine carcinoma			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Hodgkin's lymphoma			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Parathyroid tumour benign			

subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestine carcinoma			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	2 / 64 (3.13%)	1 / 60 (1.67%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	2 / 2	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic stenosis			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriosclerosis			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Deep vein thrombosis			

subjects affected / exposed	1 / 64 (1.56%)	1 / 60 (1.67%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extremity necrosis			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypertensive crisis			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Intermittent claudication			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava occlusion			

subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombosis			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pregnancy, puerperium and perinatal conditions			
Unintended pregnancy			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest Pain			
subjects affected / exposed	3 / 64 (4.69%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug ineffective			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired healing			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	3 / 64 (4.69%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 3	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Immune system disorders			
Kidney transplant rejection			
subjects affected / exposed	2 / 64 (3.13%)	3 / 60 (5.00%)	2 / 54 (3.70%)
occurrences causally related to treatment / all	0 / 2	1 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Transplant rejection			
subjects affected / exposed	6 / 64 (9.38%)	2 / 60 (3.33%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	4 / 7	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute pulmonary oedema			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemothorax			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0

Hypoxia			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory distress			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 1
Vocal cord cyst			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mental status changes			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Psychotic disorder			

subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	2 / 54 (3.70%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test abnormal			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Ankle fracture			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous fistula aneurysm			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arteriovenous fistula thrombosis			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Exposure during pregnancy			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Exposure via father			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral neck fracture			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower limb fracture			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haematuria			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal transplant failure			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			

subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant dysfunction			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant failure			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urethral injury			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound dehiscence			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Angina unstable			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure congestive			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiopulmonary failure			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Coronary artery disease			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	2 / 54 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Coronary artery dissection			

subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery occlusion			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	2 / 64 (3.13%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nervous system disorders			
Brain mass			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Complex regional pain syndrome			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			

subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxic-ischaemic encephalopathy			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	2 / 64 (3.13%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	2 / 54 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenopathy			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Tympanic membrane perforation			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

Cataract			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic gastritis			
subjects affected / exposed	2 / 64 (3.13%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 64 (0.00%)	2 / 60 (3.33%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric polyps			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	2 / 64 (3.13%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal dilatation			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Swollen tongue			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Diabetic foot			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Night sweats			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Glomerulonephritis membranous			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrotic syndrome			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal injury			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal mass			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperparathyrodism			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperparathyroidism tertiary			

subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rotator cuff syndrome			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 64 (0.00%)	2 / 60 (3.33%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis bacterial			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Aspergilloma			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atypical pneumonia			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	2 / 64 (3.13%)	2 / 60 (3.33%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	3 / 4	3 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis staphylococcal			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus chorioretinitis			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea infectious			

subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear infection			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endophthalmitis			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gas gangrene			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 64 (0.00%)	2 / 60 (3.33%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 influenza			
subjects affected / exposed	2 / 64 (3.13%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex			

subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	2 / 64 (3.13%)	2 / 60 (3.33%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	2 / 2	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 64 (0.00%)	2 / 60 (3.33%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	2 / 54 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycobacterium chelonae infection			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paronychia			

subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	4 / 64 (6.25%)	3 / 60 (5.00%)	2 / 54 (3.70%)
occurrences causally related to treatment / all	3 / 4	3 / 3	0 / 2
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia staphylococcal			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Polyomavirus-associated nephropathy			
subjects affected / exposed	0 / 64 (0.00%)	3 / 60 (5.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudomonal sepsis			
subjects affected / exposed	1 / 64 (1.56%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			

subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	2 / 64 (3.13%)	0 / 60 (0.00%)	3 / 54 (5.56%)
occurrences causally related to treatment / all	2 / 2	0 / 0	1 / 3
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 1
Sinusitis			
subjects affected / exposed	2 / 64 (3.13%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal bacteraemia			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			

subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 64 (0.00%)	3 / 60 (5.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fluid retention			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	0 / 54 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			

subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	2 / 54 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomagnesaemia			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	1 / 54 (1.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Cyclosporine	Tofacitinib Less Intensive (LI)	Tofacitinib More Intensive (MI)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	49 / 64 (76.56%)	55 / 60 (91.67%)	45 / 54 (83.33%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin papilloma			
subjects affected / exposed	4 / 64 (6.25%)	7 / 60 (11.67%)	1 / 54 (1.85%)
occurrences (all)	5	9	1
Vascular disorders			
Hypertension			
subjects affected / exposed	6 / 64 (9.38%)	4 / 60 (6.67%)	4 / 54 (7.41%)
occurrences (all)	6	4	4
Haematoma			
subjects affected / exposed	4 / 64 (6.25%)	1 / 60 (1.67%)	1 / 54 (1.85%)
occurrences (all)	4	1	1
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	7 / 64 (10.94%)	2 / 60 (3.33%)	1 / 54 (1.85%)
occurrences (all)	8	3	1
Fatigue			

subjects affected / exposed	3 / 64 (4.69%)	5 / 60 (8.33%)	5 / 54 (9.26%)
occurrences (all)	3	5	5
Peripheral swelling			
subjects affected / exposed	3 / 64 (4.69%)	6 / 60 (10.00%)	0 / 54 (0.00%)
occurrences (all)	4	6	0
Oedema peripheral			
subjects affected / exposed	4 / 64 (6.25%)	10 / 60 (16.67%)	4 / 54 (7.41%)
occurrences (all)	8	10	4
Pyrexia			
subjects affected / exposed	3 / 64 (4.69%)	7 / 60 (11.67%)	3 / 54 (5.56%)
occurrences (all)	4	8	3
Immune system disorders			
Transplant rejection			
subjects affected / exposed	5 / 64 (7.81%)	1 / 60 (1.67%)	0 / 54 (0.00%)
occurrences (all)	7	1	0
Social circumstances			
Postmenopause			
subjects affected / exposed[1]	0 / 20 (0.00%)	0 / 19 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Menorrhagia			
subjects affected / exposed[2]	0 / 20 (0.00%)	1 / 19 (5.26%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Vulval disorder			
subjects affected / exposed[3]	0 / 20 (0.00%)	1 / 19 (5.26%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 64 (4.69%)	4 / 60 (6.67%)	6 / 54 (11.11%)
occurrences (all)	3	4	8
Dyspnoea			
subjects affected / exposed	3 / 64 (4.69%)	2 / 60 (3.33%)	3 / 54 (5.56%)
occurrences (all)	4	2	3
Psychiatric disorders			
Anxiety			

subjects affected / exposed	1 / 64 (1.56%)	5 / 60 (8.33%)	4 / 54 (7.41%)
occurrences (all)	2	7	4
Depression			
subjects affected / exposed	2 / 64 (3.13%)	4 / 60 (6.67%)	0 / 54 (0.00%)
occurrences (all)	2	4	0
Insomnia			
subjects affected / exposed	6 / 64 (9.38%)	3 / 60 (5.00%)	0 / 54 (0.00%)
occurrences (all)	6	3	0
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	3 / 64 (4.69%)	4 / 60 (6.67%)	5 / 54 (9.26%)
occurrences (all)	4	4	5
Cardiac murmur			
subjects affected / exposed	2 / 64 (3.13%)	4 / 60 (6.67%)	4 / 54 (7.41%)
occurrences (all)	2	4	4
Blood creatinine increased			
subjects affected / exposed	7 / 64 (10.94%)	1 / 60 (1.67%)	2 / 54 (3.70%)
occurrences (all)	8	2	2
Weight decreased			
subjects affected / exposed	2 / 64 (3.13%)	5 / 60 (8.33%)	0 / 54 (0.00%)
occurrences (all)	2	5	0
Weight increased			
subjects affected / exposed	4 / 64 (6.25%)	5 / 60 (8.33%)	3 / 54 (5.56%)
occurrences (all)	4	5	3
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	4 / 64 (6.25%)	4 / 60 (6.67%)	6 / 54 (11.11%)
occurrences (all)	4	6	6
Nervous system disorders			
Dizziness			
subjects affected / exposed	4 / 64 (6.25%)	2 / 60 (3.33%)	2 / 54 (3.70%)
occurrences (all)	5	2	2
Headache			
subjects affected / exposed	8 / 64 (12.50%)	7 / 60 (11.67%)	3 / 54 (5.56%)
occurrences (all)	9	9	4
Tremor			

subjects affected / exposed	1 / 64 (1.56%)	1 / 60 (1.67%)	3 / 54 (5.56%)
occurrences (all)	1	1	3
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	8 / 64 (12.50%)	1 / 60 (1.67%)	3 / 54 (5.56%)
occurrences (all)	9	2	6
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	4 / 64 (6.25%)	4 / 60 (6.67%)	1 / 54 (1.85%)
occurrences (all)	4	5	1
Abdominal Pain			
subjects affected / exposed	4 / 64 (6.25%)	7 / 60 (11.67%)	1 / 54 (1.85%)
occurrences (all)	4	8	1
Constipation			
subjects affected / exposed	4 / 64 (6.25%)	4 / 60 (6.67%)	2 / 54 (3.70%)
occurrences (all)	7	4	2
Diarrhoea			
subjects affected / exposed	10 / 64 (15.63%)	9 / 60 (15.00%)	4 / 54 (7.41%)
occurrences (all)	12	9	5
Nausea			
subjects affected / exposed	6 / 64 (9.38%)	7 / 60 (11.67%)	2 / 54 (3.70%)
occurrences (all)	12	7	2
Vomiting			
subjects affected / exposed	9 / 64 (14.06%)	8 / 60 (13.33%)	2 / 54 (3.70%)
occurrences (all)	12	8	2
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 64 (0.00%)	2 / 60 (3.33%)	3 / 54 (5.56%)
occurrences (all)	0	2	3
Actinic keratosis			
subjects affected / exposed	2 / 64 (3.13%)	4 / 60 (6.67%)	2 / 54 (3.70%)
occurrences (all)	2	4	2
Alopecia			
subjects affected / exposed	1 / 64 (1.56%)	6 / 60 (10.00%)	2 / 54 (3.70%)
occurrences (all)	1	7	2
Hirsutism			

subjects affected / exposed[4]	2 / 20 (10.00%)	0 / 19 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Pruritus			
subjects affected / exposed	0 / 64 (0.00%)	5 / 60 (8.33%)	1 / 54 (1.85%)
occurrences (all)	0	5	1
Rash			
subjects affected / exposed	0 / 64 (0.00%)	3 / 60 (5.00%)	4 / 54 (7.41%)
occurrences (all)	0	3	4
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 64 (1.56%)	5 / 60 (8.33%)	1 / 54 (1.85%)
occurrences (all)	1	5	1
Proteinuria			
subjects affected / exposed	4 / 64 (6.25%)	4 / 60 (6.67%)	3 / 54 (5.56%)
occurrences (all)	4	4	3
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	10 / 64 (15.63%)	8 / 60 (13.33%)	7 / 54 (12.96%)
occurrences (all)	12	9	7
Back pain			
subjects affected / exposed	8 / 64 (12.50%)	4 / 60 (6.67%)	2 / 54 (3.70%)
occurrences (all)	11	4	2
Musculoskeletal pain			
subjects affected / exposed	3 / 64 (4.69%)	2 / 60 (3.33%)	3 / 54 (5.56%)
occurrences (all)	3	2	3
Pain in extremity			
subjects affected / exposed	4 / 64 (6.25%)	8 / 60 (13.33%)	2 / 54 (3.70%)
occurrences (all)	4	14	3
Infections and infestations			
BK virus infection			
subjects affected / exposed	0 / 64 (0.00%)	6 / 60 (10.00%)	1 / 54 (1.85%)
occurrences (all)	0	8	1
Bronchitis			
subjects affected / exposed	4 / 64 (6.25%)	4 / 60 (6.67%)	1 / 54 (1.85%)
occurrences (all)	6	4	1
Epstein-Barr viraemia			

subjects affected / exposed	1 / 64 (1.56%)	1 / 60 (1.67%)	3 / 54 (5.56%)
occurrences (all)	1	1	3
Fungal skin infection			
subjects affected / exposed	0 / 64 (0.00%)	1 / 60 (1.67%)	3 / 54 (5.56%)
occurrences (all)	0	1	3
Gastroenteritis			
subjects affected / exposed	2 / 64 (3.13%)	6 / 60 (10.00%)	2 / 54 (3.70%)
occurrences (all)	2	6	2
Herpes zoster			
subjects affected / exposed	3 / 64 (4.69%)	11 / 60 (18.33%)	5 / 54 (9.26%)
occurrences (all)	3	12	6
Nasopharyngitis			
subjects affected / exposed	5 / 64 (7.81%)	4 / 60 (6.67%)	3 / 54 (5.56%)
occurrences (all)	8	5	4
Onychomycosis			
subjects affected / exposed	2 / 64 (3.13%)	7 / 60 (11.67%)	2 / 54 (3.70%)
occurrences (all)	2	7	2
Urinary tract infection			
subjects affected / exposed	4 / 64 (6.25%)	4 / 60 (6.67%)	5 / 54 (9.26%)
occurrences (all)	5	5	5
Upper respiratory tract infection			
subjects affected / exposed	7 / 64 (10.94%)	10 / 60 (16.67%)	13 / 54 (24.07%)
occurrences (all)	9	18	15
Metabolism and nutrition disorders			
Hyperlipidaemia			
subjects affected / exposed	2 / 64 (3.13%)	1 / 60 (1.67%)	5 / 54 (9.26%)
occurrences (all)	2	1	5
Hypercholesterolaemia			
subjects affected / exposed	1 / 64 (1.56%)	4 / 60 (6.67%)	1 / 54 (1.85%)
occurrences (all)	1	5	1
Hypertriglyceridaemia			
subjects affected / exposed	0 / 64 (0.00%)	2 / 60 (3.33%)	3 / 54 (5.56%)
occurrences (all)	0	2	3
Hypokalaemia			
subjects affected / exposed	4 / 64 (6.25%)	1 / 60 (1.67%)	2 / 54 (3.70%)
occurrences (all)	4	1	6

Impaired fasting glucose			
subjects affected / exposed	0 / 64 (0.00%)	0 / 60 (0.00%)	3 / 54 (5.56%)
occurrences (all)	0	0	3
Vitamin D deficiency			
subjects affected / exposed	1 / 64 (1.56%)	0 / 60 (0.00%)	3 / 54 (5.56%)
occurrences (all)	1	0	3

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The adverse event is gender-specific. The total numbers of subjects exposed refers to female subjects only and hence is less than the total number of subjects exposed for the reporting group

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The adverse event is gender-specific. The total numbers of subjects exposed refers to female subjects only and hence is less than the total number of subjects exposed for the reporting group

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The adverse event is gender-specific. The total numbers of subjects exposed refers to female subjects only and hence is less than the total number of subjects exposed for the reporting group

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The adverse event is gender-specific. The total numbers of subjects exposed refers to female subjects only and hence is less than the total number of subjects exposed for the reporting group

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 May 2009	Required subjects to decrease their tofacitinib dose to 5mg BID by Month 18 posttransplant
26 March 2010	Extension of the duration of the A3921050 trial by an additional 3 years through 6 years posttransplant
04 November 2010	Discontinuation of subjects with tofacitinib exposure (measured by TWC2 above median) at 6 months posttransplant
28 February 2011	Discontinuation of CP-690,550 treated subjects whose EBV serostatus at the time of transplantation was either negative or unknown, have developed CMV disease or have received lymphocyte depleting agents posttransplant
17 December 2012	Updated the compound identifiers and template language to comply with the Food and Drug Administration (FDA) Final Rule and/or the European Union 'CT-3' guidance

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported