Clinical trial results:
A 12-month randomized, multiple dose, open-label, study evaluating safety, tolerability, pharmacokinetics/pharmacodynamics (PK/PD) and efficacy of an anti-CD40 monoclonal antibody, CFZ533, in combination with mycophenolate mofetil (MMF) and corticosteroids (CS), with and without tacrolimus (Tac), in de novo renal transplant recipients

Summary

EudraCT number	2015-000925-36
Trial protocol	DE NL ES
Global end of trial date	29 November 2017

Results information

Result version number	v1 (current)
This version publication date	12 December 2018
First version publication date	12 December 2018

Trial information

Trial identification

Sponsor protocol code	CCFZ533X2201

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02217410
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@novartis.com
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, Novartis.email@novartis.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	29 November 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 November 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the safety, tolerability and PK of multiple IV and SC doses of CFZ533 in combination with MMF, CS, and Tac (standard exposure) in de novo renal transplant patients over the treatment and follow-up period.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 February 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 19
Country: Number of subjects enrolled	Netherlands: 11
Country: Number of subjects enrolled	Germany: 22
Country: Number of subjects enrolled	Brazil: 7
Worldwide total number of subjects	59
EEA total number of subjects	33

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)	47
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

In Part 1, patients were enrolled into Arm 1. In Part 2, patients were randomized (2:1) to Arms 2A and 2B.

Pre-assignment

Screening details:

Study Part 1 focused on measuring the multiple-dose safety, tolerability, PK, and PD of both IV and SC CFZ533 when administered with the SoC treatment regimen. Study Part 2 investigated efficacy, safety, tolerability, PK and PD of CFZ533 in the absence of Tac.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	CFZ533 + TAC + MMF (part 1)

Arm description:

CFZ533 (3 mg/kg SC) administered with the contemporary standard of care (SoC) consists of concentration-controlled tacrolimus (Tac), combined with mycophenolate mofetil (MMF) and corticosteroids (CS).

Arm type	Experimental
Investigational medicinal product name	CFZ533
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for cutaneous solution, Concentrate for solution for injection/infusion
Routes of administration	Intravascular use , Intravenous use

Dosage and administration details:

CFZ533 was supplied as 150 mg/mL lyophilized open-label bulk medication requiring reconstitution. 3 mg/kg CFZ533 was administered IV pre-transplant or intra-operatively on Day 1 and subsequently CFZ533 SC was administered for a period of 3 months. MMF (CellCept® or Generics) was taken as 2 tablets of 500 mg or 4 capsules of 250 mg BID (2 g/day) or as per local practice. For patients who remained intubated >24 hours posttransplant and/or whom were otherwise unable to swallow oral medication, IV MMF was substituted until oral conversion was possible. The first dose of MMF was administered within 24 hours after graft reperfusion of the allograft or according to local practice.

Arm title	CFZ533 + MMF (part 2)

Arm description:

CFZ533 (10mg/kg IV) administered with mycophenolate mofetil (MMF) and corticosteroids (CS) with anti-IL2 induction

Arm type	Experimental
Investigational medicinal product name	CFZ533
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for cutaneous solution, Concentrate for solution for injection/infusion
Routes of administration	Intravascular use , Intravenous use

Dosage and administration details:

CFZ533 was supplied as 150 mg/mL lyophilized open-label bulk medication requiring reconstitution. CFZ533 150 mg/mL concentrate for solution for infusion/ solution for injection (liquid in vial) was introduced in Part 2. 10 mg/kg CFZ533 was administered IV pre-transplant or intra-operatively on Day 1

and subsequently CFZ533 IV was administered for 12 months. MMF (CellCept® or Generics) was taken as 2 tablets of 500 mg or 4 capsules of 250 mg BID (2 g/day) or as per local practice. For patients who remained intubated >24 hours post-transplant and/or whom were otherwise unable to swallow oral medication, IV MMF was substituted until oral conversion was possible. The first dose of MMF was administered within 24 hours after graft reperfusion of the allograft or according to local practice.

Arm title	Tac + MMF (part 2)

Arm description:

Standard of care (SoC) [concentration-controlled tacrolimus (Tac) combined with mycophenolate mofetil (MMF) and corticosteroids (CS) with anti-IL2 induction]

Arm type	Active comparator
Investigational medicinal product name	Either Prograf® or Generics
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Tac was administered as taken by mouth (PO) capsules twice a day (BID) and adjusted to maintain within the target ranges of 4-11 ng/mL. Tac was initiated within 24 hours after reperfusion of the graft. MMF (CellCept® or Generics) was taken as 2 tablets of 500 mg or 4 capsules of 250 mg BID (2 g/day) or as per local practice. For patients who remained intubated >24 hours post-transplant and/or whom were otherwise unable to swallow oral medication, IV MMF was substituted until oral conversion was possible. The first dose of MMF was administered within 24 hours after graft reperfusion of the allograft or according to local practice.

Number of subjects in period 1	CFZ533 + TAC + MMF (part 1)	CFZ533 + MMF (part 2)	Tac + MMF (part 2)
Started	7	34	18
Completed	6	30	13
Not completed	1	4	5
Physician decision	1	3	-
Graft Loss	-	-	2
Consent withdrawn by subject	-	-	2
Lost to follow-up	-	-	1
Lack of efficacy	-	1	-

Baseline characteristics

Reporting groups	
Reporting group title	CFZ533 + TAC + MMF (part 1)
Reporting group description:	
CFZ533 (3 mg/kg SC) administered with the contemporary standard of care (SoC) consists of concentration-controlled tacrolimus (Tac), combined with mycophenolate mofetil (MMF) and corticosteroids (CS).	
Reporting group title	CFZ533 + MMF (part 2)
Reporting group description:	
CFZ533 (10mg/kg IV) administered with mycophenolate mofetil (MMF) and corticosteroids (CS) with anti-IL2 induction	
Reporting group title	Tac + MMF (part 2)
Reporting group description:	
Standard of care (SoC) [concentration-controlled tacrolimus (Tac) combined with mycophenolate mofetil (MMF) and corticosteroids (CS) with anti-IL2 induction]	

Reporting group values	CFZ533 + TAC + MMF (part 1)	CFZ533 + MMF (part 2)	Tac + MMF (part 2)
Number of subjects	7	34	18
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	6	30	11
From 65-84 years	1	4	7
85 years and over	0	0	0
Age Continuous Units: years			
arithmetic mean	48.1	49.0	53.4
standard deviation	± 9.30	± 15.79	± 18.01
Sex: Female, Male Units: Subjects			
Female	3	8	6
Male	4	26	12
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	2	20	9
Unknown or Not Reported	5	13	9

Reporting group values	Total		
Number of subjects	59		

Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	47		
From 65-84 years	12		
85 years and over	0		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: Subjects			
Female	17		
Male	42		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1		
Not Hispanic or Latino	31		
Unknown or Not Reported	27		

End points

End points reporting groups

Reporting group title	CFZ533 + TAC + MMF (part 1)
Reporting group description:	
CFZ533 (3 mg/kg SC) administered with the contemporary standard of care (SoC) consists of concentration-controlled tacrolimus (Tac), combined with mycophenolate mofetil (MMF) and corticosteroids (CS).	
Reporting group title	CFZ533 + MMF (part 2)
Reporting group description:	
CFZ533 (10mg/kg IV) administered with mycophenolate mofetil (MMF) and corticosteroids (CS) with anti-IL2 induction	
Reporting group title	Tac + MMF (part 2)
Reporting group description:	
Standard of care (SoC) [concentration-controlled tacrolimus (Tac) combined with mycophenolate mofetil (MMF) and corticosteroids (CS) with anti-IL2 induction]	
Subject analysis set title	sCD40 (part I)
Subject analysis set type	Safety analysis
Subject analysis set description:	
CFZ533 (3 mg/kg SC) administered with the contemporary standard of care (SoC) consists of concentration-controlled tacrolimus (Tac), combined with mycophenolate mofetil (MMF) and corticosteroids (CS).	
Subject analysis set title	sCD154
Subject analysis set type	Safety analysis
Subject analysis set description:	
CFZ533 (3 mg/kg SC) administered with the contemporary standard of care (SoC) consists of concentration-controlled tacrolimus (Tac), combined with mycophenolate mofetil (MMF) and corticosteroids (CS).	
Subject analysis set title	Free CD40 on whole blood B ceels
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
CFZ533 (10mg/kg IV) administered with mycophenolate mofetil (MMF) and corticosteroids (CS) with anti-IL2 induction	
Subject analysis set title	Total CD40 on whole blood B cells
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
CFZ533 (10mg/kg IV) administered with mycophenolate mofetil (MMF) and corticosteroids (CS) with anti-IL2 induction	

Primary: Mean Cmax Pharmacokinetic Parameter- Part I

End point title	Mean Cmax Pharmacokinetic Parameter- Part I[1][2]
End point description:	
Pharmacokinetics as defined by the systemic concentrations and Cmax of certain immunosuppressant medications used in Part I	
End point type	Primary
End point timeframe:	
Day 1	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: descriptive statistics

[2] - 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: descriptive statistics

End point values	CFZ533 + TAC + MMF (part 1)			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: ug/mL				
arithmetic mean (standard deviation)	66.3 (± 12.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean Tmax Pharmacokinetic Parameter - Part I

End point title	Mean Tmax Pharmacokinetic Parameter - Part I[3][4]

End point description:

Quantify pharmacokinetics of CFZ533 in combination with MMF, CS, and tacrolimus in de novo renal transplant patients during the treatment and follow-up periods.

End point type	Primary

End point timeframe:

Day 1

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: descriptive statistics

[4] - 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: descriptive statistics

End point values	CFZ533 + TAC + MMF (part 1)			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: day				
median (full range (min-max))	0.237 (0 to 1.02)			

Statistical analyses

No statistical analyses for this end point

Primary: Mean AUClast Pharmacokinetic Parameter - Part I

End point title	Mean AUClast Pharmacokinetic Parameter - Part I[5][6]

End point description:

Quantify pharmacokinetics of CFZ533 in combination with MMF, CS, and tacrolimus in de novo renal transplant patients during the treatment and follow-up periods.

End point type	Primary

End point timeframe:

Day 1

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: descriptive statistics

[6] - 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: descriptive statistics

End point values	CFZ533 + TAC + MMF (part 1)			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: day*ug/mL				
arithmetic mean (standard deviation)	367 (± 52.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Efficacy as defined by the frequency and severity (Banff classification) of treated biopsy proven acute rejection (tBPAR) adjudicated data - Part II

End point title	Efficacy as defined by the frequency and severity (Banff classification) of treated biopsy proven acute rejection (tBPAR) adjudicated data - Part II[7]

End point description:

To assess the activity of the investigational arm as compared to the standard of care control arm in de novo renal transplant patients as measured by the frequency and severity of tBPAR as measured on the Banff classification scale. An adjudication was performed on all on cause renal biopsies by an independent expert committee blinded to therapy.

End point type	Primary

End point timeframe:

3, 6, 9, and 12 months

Notes:

[7] - 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: descriptive statistics

End point values	CFZ533 + MMF (part 2)	Tac + MMF (part 2)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33	18		
Units: events				
Month 3|	6	2		
Month 6|	7	3		
Month 9|	7	3		
Month 12|	7	3		

Statistical analyses

Statistical analysis title	Frequency and severity of tBPAR-adjudicated data
Statistical analysis description: Banff classification	
Comparison groups	CFZ533 + MMF (part 2) v Tac + MMF (part 2)
Number of subjects included in analysis	51
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8976
Method	Bayesian posterior probability
Parameter estimate	Mean difference (final values)
Point estimate	0.095
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.067
upper limit	0.263

Statistical analysis title	Frequency and severity of tBPAR-adjudicated data
Statistical analysis description: Banff classification	
Comparison groups	CFZ533 + MMF (part 2) v Tac + MMF (part 2)
Number of subjects included in analysis	51
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8836
Method	Bayesian posterior probability
Parameter estimate	Mean difference (final values)
Point estimate	0.093
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.084
upper limit	0.271

Statistical analysis title	Frequency and severity of tBPAR-adjudicated data
Statistical analysis description: Banff classification	
Comparison groups	CFZ533 + MMF (part 2) v Tac + MMF (part 2)
Number of subjects included in analysis	51
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8822
Method	Bayesian posterior probability
Parameter estimate	Mean difference (final values)
Point estimate	0.093

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.085
upper limit	0.272

Statistical analysis title	Frequency and severity of tBPAR-adjudicated data
Statistical analysis description:	
Banff classification	
Comparison groups	CFZ533 + MMF (part 2) v Tac + MMF (part 2)
Number of subjects included in analysis	51
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8821
Method	Bayesian posterior probability
Parameter estimate	Mean difference (final values)
Point estimate	0.093
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.087
upper limit	0.273

Secondary: Total soluble CD40 and total soluble CD154 concentrations in plasma - Part 1

End point title	Total soluble CD40 and total soluble CD154 concentrations in plasma - Part 1
End point description:	
To quantify the change from baseline and recovery of peripheral blood total soluble CD40 and total soluble CD154	
End point type	Secondary
End point timeframe:	
Baseline to end of study (Day 1, Day 29, Day 337)	

End point values	sCD40 (part I)	sCD154		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	7	7		
Units: ng/ml				
arithmetic mean (standard deviation)				
Baseline|	4.03 (± 4.08)	0.125 (± 0.007)		
Day 1|	8.86 (± 0.0585)	0.0585 (± 0.0711)		
Day 2|	16.7 (± 4.51)	0.139 (± 0.193)		

Day 3|	24.8 (± 4.47)	0.157 (± 0.235)		
Day 4|	31.3 (± 6.34)	0.241 (± 0.418)		
Day 8|	54.0 (± 11.2)	0.399 (± 0.636)		
Day 15|	84.1 (± 13.8)	0.0879 (± 0.139)		
Day 22|	102 (± 13.9)	0.0500 (± 0.132)		
Day 29|	120 (± 15.7)	0.225 (± 0.504)		
Day 36|	128 (± 19.2)	0.116 (± 0.2)		
Day 43|	145 (± 25.6)	0.0193 (± 0.0474)		
Day 50|	156 (± 6.35)	0.0478 (± 0.0687)		
Day 57|	161 (± 21.2)	0 (± 0)		
Day 64|	163 (± 24.2)	0.0316 (± 0.0492)		
Day 71|	156 (± 19.2)	0.0148 (± 0.0363)		
Day 85|	168 (± 21.4)	0.0139 (± 0.0340)		
Day 99|	155 (± 23.3)	0 (± 0)		
Day 113|	85.7 (± 47.9)	0.0668 (± 0.164)		
Day 127|	12.2 (± 15.7)	0.0488 (± 0.0697)		
EoS|	0.918 (± 0.330)	0.0184 (± 0.0411)		

Statistical analyses

No statistical analyses for this end point

Secondary: Free CD40 and total CD40 on B cells - Part II

End point title	Free CD40 and total CD40 on B cells - Part II

End point description:

The magnitude and duration of peripheral blood CD40 occupancy. MESF: molecules of equivalent soluble fluorochrome

End point type	Secondary

End point timeframe:

Baseline to end of study (Day 1/predose)

End point values	Free CD40 on whole blood B ceels	Total CD40 on whole blood B cells		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	26	29		
Units: MESF				
arithmetic mean (standard deviation)				

CFZ553 + MMF (Baseline)|	30836.00 (± 13648.69)	12778.80 (± 7873.76)		
CFZ553 + MMF (D1 - 6h post dose)|	1623.81 (± 1359.85)	13806.90 (± 7185.66)		
CFZ553 + MMF (D15)|	799.62 (± 762.38)	15160.38 (± 7398.57)		
CFZ553 + MMF (D 29)|	817.63 (± 1540.16)	13299.60 (± 6330.89)		
CFZ553 + MMF (D 57)|	597.13 (± 523.55)	12234.38 (± 6943.13)		
CFZ553 + MMF (D 85)|	635.47 (± 614.68)	9330.86 (± 8484.46)		
CFZ553 + MMF (D 197)|	3699.0 (± 7298.98)	2820.72 (± 2347.11)		
CFZ553 + MMF (253)|	2667.38 (± 6146.86)	1427.14 (± 740.48)		
CFZ553 + MMF (EoS)|	176.17 (± 266.82)	1069.67 (± 809.12)		
Tac + MMF (Baseline)|	31508.33 (± 12759.49)	14581.43 (± 9342.79)		
Tac + MMF (D1 - 6h post dose)|	26437.65 (± 11930.50)	13715.00 (± 8293.33)		
Tac + MMF (D15)|	24441.67 (± 9125.93)	13707.14 (± 6770.14)		
Tac + MMF (D29)|	27840.00 (± 12106.72)	12698.75 (± 6002.96)		
Tac + MMF (D57)|	27994.29 (± 12004.57)	12583.85 (± 6210.07)		
Tac + MMF (D85)|	25044.00 (± 10896.65)	8701.54 (± 4183.00)		
Tac + MMF (D197)|	21360.00 (± 3155.67)	2067.60 (± 1617.28)		
Tac + MMF (D253)|	15752.75 (± 7145.32)	1750.50 (± 1005.84)		
Tac + MMF (EoS)|	21200.00 (± 4407.95)	6276.17 (± 11271.20)		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-CFZ533 antibodies - Part I

End point title	Anti-CFZ533 antibodies - Part I[8]

End point description:

To evaluate the immunogenicity of CFZ533 via the quantitative analysis of anti-CFZ533 antibodies

End point type	Secondary

End point timeframe:

Baseline to end of study

Notes:

[8] - 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: descriptive statistics

End point values	CFZ533 + TAC + MMF (part 1)			
Subject group type	Reporting group			
Number of subjects analysed	7			
Units: anti-CFZ533 antibodies	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-CFZ533 antibodies - Part II

End point title	Anti-CFZ533 antibodies - Part II[9]

End point description:

To evaluate the immunogenicity of CFZ533 via the quantitative analysis of anti-CFZ533 antibodies

End point type	Secondary

End point timeframe:

Baseline to end of study (screening, baseline, Day 141, Day 225, Day 309, Study Completion)

Notes:

[9] - 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: descriptive statistics

End point values	CFZ533 + MMF (part 2)	Tac + MMF (part 2)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	34	18		
Units: anti-CFZ533 antibodies				
Screening|	0	0		
Baseline|	0	0		
Day 141|	0	0		
Day 225|	0	0		
Day 309|	0	0		
Study Completion|	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: eGFR - Part II

End point title	eGFR - Part II[10]

End point description:

Renal function as assessed by MDRD (Modification of Diet in Renal Disease) formula. eGFR: Estimated glomerular filtration rate

End point type	Secondary

End point timeframe:

Day 1, Day 29, Day 337,

Notes:

[10] - 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: descriptive statistics

End point values	CFZ533 + MMF (part 2)	Tac + MMF (part 2)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	32	18		
Units: ml/min				
arithmetic mean (confidence interval 90%)				
Day 1|	9.8 (8.3 to 11.3)	9.7 (7.7 to 11.8)		
Day 29|	55.6 (50.4 to 60.7)	44.3 (37.2 to 51.4)		
Day 337|	58.2 (52.2 to 64.2)	44.2 (36.1 to 52.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: CFZ533 plasma PK concentrations - Part II

End point title	CFZ533 plasma PK concentrations - Part II[11]

End point description:

Quantify the systemic concentrations of CFZ533 in combination with MMF, CS, and tacrolimus in de novo renal transplant patients during the treatment and follow-up periods. A full pharmacokinetic analysis can be performed on the concentration-time data to evaluate the impact of renal transplantation on the various medications used in the treatment regimen.

End point type	Secondary

End point timeframe:

throughout study period (day 1 to day 336)

Notes:

[11] - 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: descriptive statistics

End point values	CFZ533 + MMF (part 2)			
Subject group type	Reporting group			
Number of subjects analysed	32			
Units: ug/mL				
arithmetic mean (standard deviation)				
Day 1|	150 (± 42.8)			
Day 2|	148 (± 77.5)			
Day 3|	277 (± 91.3)			
Day 14|	262 (± 59.8)			
Day 28|	258 (± 52.8)			
Day 56|	306 (± 61.0)			
Day 84|	247 (± 58.2)			

Day 112|	211 (± 51.8)			
Day 140|	178 (± 54.9)			
Day 168|	157 (± 57.4)			
Day 196|	148 (± 53.1)			
Day 224|	147 (± 53.8)			
Day 252|	151 (± 35.2)			
Day 280|	160 (± 87.7)			
Day 308|	132 (± 42.5)			
Day 336|	156 (± 85.2)			
End of study|	133 (± 57.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: Total sCD40 plasma concentrations - Part II

End point title	Total sCD40 plasma concentrations - Part II[12]

End point description:

To quantify the change from baseline and recovery of peripheral blood total soluble CD40

End point type	Secondary

End point timeframe:

12 months

Notes:

[12] - 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: descriptive statistics

End point values	CFZ533 + MMF (part 2)	Tac + MMF (part 2)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	32	17		
Units: ng/mL				
arithmetic mean (standard deviation)				
Baseline|	3.02 (± 2.44)	3.67 (± 2.15)		
Day 1|	6.95 (± 4.29)	1.16 (± 1.15)		
Day 4|	24.6 (± 11.0)	1.16 (± 1.15)		
Day 15|	69.6 (± 21.5)	0.869 (± 1.55)		
Day 29|	101 (± 18.9)	0.362 (± 0.0746)		
Day 57|	140 (± 17.4)	0.438 (± 0.316)		
Day 85|	189 (± 76.4)	0.429 (± 0.324)		
Day 113|	215 (± 75.5)	0.391 (± 0.129)		
Day 141|	237 (± 93.1)	0.453 (± 0.271)		
Day 169|	238 (± 80.3)	0.537 (± 0.215)		
Day 197|	253 (± 81.3)	0.423 (± 0.0908)		

Day 225|	258 (± 77.7)	0.452 (± 0.119)		
Day 253|	236 (± 36.5)	0.457 (± 0.0800)		
Day 281|	273 (± 71.3)	0.455 (± 0.0789)		
Day 309|	286 (± 66.0)	0.454 (± 0.0957)		
Day 337|	298 (± 57.4)	0.411 (± 0.0581)		
End of Study|	303 (± 59.7)	0.959 (± 1.88)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Adverse Events (AEs) are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All AEs reported in this record are from date of First Patient First Treatment until Last Patient Last Visit) up to approximately 3 years.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	20.1

Reporting groups	
Reporting group title	CFZ533 + TAC + MMF (part 1)
Reporting group description:	
CFZ533 (3 mg/kg SC) administered with the contemporary standard of care (SoC) consists of concentrationcontrolled tacrolimus (Tac), combined with mycophenolate mofetil (MMF) and corticosteroids (CS)	
Reporting group title	CFZ533 + MMF (part 2)
Reporting group description:	
CFZ533 (10mg/kg IV) administered with mycophenolate mofetil (MMF) and corticosteroids (CS) with anti-IL2 induction	
Reporting group title	Tac + MMF (part 2)
Reporting group description:	
Standard of care (SoC) [concentration-controlled tacrolimus (Tac) combined with mycophenolate mofetil (MMF) and corticosteroids (CS) with anti-IL2 induction]	
Reporting group title	Total
Reporting group description:	
Total	

Serious adverse events	CFZ533 + TAC + MMF (part 1)	CFZ533 + MMF (part 2)	Tac + MMF (part 2)
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 7 (57.14%)	21 / 34 (61.76%)	12 / 18 (66.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basosquamous carcinoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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

Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (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
Hypertension			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (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
Hypertensive crisis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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
Lymphocele			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic venous thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Kidney transplant rejection			
subjects affected / exposed	0 / 7 (0.00%)	5 / 34 (14.71%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	5 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant rejection			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	0 / 18 (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
Respiratory, thoracic and mediastinal disorders			
Cough			

subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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
Pneumothorax			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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
Pulmonary embolism			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (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
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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
Investigations			
Amylase increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
White blood cell count decreased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (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, poisoning and procedural complications			
Arteriovenous fistula aneurysm			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Complications of transplanted kidney			
subjects affected / exposed	1 / 7 (14.29%)	1 / 34 (2.94%)	2 / 18 (11.11%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delayed graft function			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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
Graft loss			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	2 / 18 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated incisional hernia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant dysfunction			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transplant failure			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tricuspid valve incompetence			

subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 7 (14.29%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
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			
Photophobia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (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
Vision blurred			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 7 (14.29%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			

subjects affected / exposed	1 / 7 (14.29%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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
Gastrointestinal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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
Inguinal hernia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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
Mouth ulceration			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (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
Nausea			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (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
Pancreatitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (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
Retroperitoneal haematoma			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	0 / 18 (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
Vomiting			

subjects affected / exposed	2 / 7 (28.57%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal tubular necrosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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 retention			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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
Cytomegalovirus infection			
subjects affected / exposed	0 / 7 (0.00%)	3 / 34 (8.82%)	2 / 18 (11.11%)
occurrences causally related to treatment / all	0 / 0	2 / 3	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterobacter bacteraemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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
Gastroenteritis			

subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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
Gastrointestinal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis C			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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 / 7 (0.00%)	4 / 34 (11.76%)	1 / 18 (5.56%)
occurrences causally related to treatment / all	0 / 0	2 / 4	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	3 / 18 (16.67%)
occurrences causally related to treatment / all	0 / 0	1 / 2	3 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cyst infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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
Urosepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	2 / 18 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (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
Hyperglycaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (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
Hyperkalaemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (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

Serious adverse events	Total		
Total subjects affected by serious adverse events			
subjects affected / exposed	37 / 59 (62.71%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basosquamous carcinoma			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	3 / 3		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertension			

subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertensive crisis			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lymphocele			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pelvic venous thrombosis			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Kidney transplant rejection			
subjects affected / exposed	6 / 59 (10.17%)		
occurrences causally related to treatment / all	5 / 7		
deaths causally related to treatment / all	0 / 0		
Transplant rejection			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Pulmonary embolism				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Mental status changes				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Investigations				
Amylase increased				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Blood creatinine increased				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
White blood cell count decreased				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Arteriovenous fistula aneurysm				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Complications of transplanted kidney				
subjects affected / exposed	4 / 59 (6.78%)			
occurrences causally related to treatment / all	1 / 4			
deaths causally related to treatment / all	0 / 0			
Delayed graft function				

subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Graft loss			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Incarcerated incisional hernia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Incisional hernia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Transplant dysfunction			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Transplant failure			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Tricuspid valve incompetence			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			

Headache			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pancytopenia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Photophobia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vision blurred			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	3 / 59 (5.08%)		
occurrences causally related to treatment / all	2 / 3		
deaths causally related to treatment / all	0 / 0		
Diarrhoea haemorrhagic			

subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal inflammation				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Inguinal hernia				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Mouth ulceration				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Retroperitoneal haematoma				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	3 / 59 (5.08%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Acute kidney injury				

subjects affected / exposed	2 / 59 (3.39%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Renal tubular necrosis				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary retention				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Bacteraemia				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Cytomegalovirus infection				
subjects affected / exposed	5 / 59 (8.47%)			
occurrences causally related to treatment / all	3 / 5			
deaths causally related to treatment / all	0 / 0			
Encephalitis				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Enterobacter bacteraemia				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal infection				

subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatitis C				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumocystis jirovecii pneumonia				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Polyomavirus-associated nephropathy				
subjects affected / exposed	5 / 59 (8.47%)			
occurrences causally related to treatment / all	2 / 5			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	5 / 59 (8.47%)			
occurrences causally related to treatment / all	4 / 6			
deaths causally related to treatment / all	0 / 0			
Renal cyst infection				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urosepsis				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Dehydration				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				

subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperkalaemia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	CFZ533 + TAC + MMF (part 1)	CFZ533 + MMF (part 2)	Tac + MMF (part 2)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	33 / 34 (97.06%)	18 / 18 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Haematoma			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Hot flush			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Hypertension			
subjects affected / exposed	1 / 7 (14.29%)	13 / 34 (38.24%)	6 / 18 (33.33%)
occurrences (all)	1	13	7
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	3 / 18 (16.67%)
occurrences (all)	0	2	3
Lymphocele			

subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Orthostatic hypotension			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Poor venous access			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Catheter site pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Chills			
subjects affected / exposed	0 / 7 (0.00%)	3 / 34 (8.82%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Cyst			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	1 / 7 (14.29%)	5 / 34 (14.71%)	5 / 18 (27.78%)
occurrences (all)	1	5	5
Generalised oedema			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Impaired healing			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	1 / 18 (5.56%)
occurrences (all)	0	2	1
Influenza like illness			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Infusion site swelling			

subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	2 / 7 (28.57%)	7 / 34 (20.59%)	6 / 18 (33.33%)
occurrences (all)	3	11	8
Pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	2
Secretion discharge			
subjects affected / exposed	3 / 7 (42.86%)	0 / 34 (0.00%)	0 / 18 (0.00%)
occurrences (all)	3	0	0
Swelling			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Kidney transplant rejection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Dysmenorrhoea			

subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Erectile dysfunction			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Menorrhagia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Penile oedema			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Penile pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Prostatomegaly			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Scrotal swelling			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 7 (0.00%)	10 / 34 (29.41%)	2 / 18 (11.11%)
occurrences (all)	0	13	2
Dyspnoea			
subjects affected / exposed	3 / 7 (42.86%)	2 / 34 (5.88%)	3 / 18 (16.67%)
occurrences (all)	3	3	3
Dyspnoea exertional			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Lung infiltration			

subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 7 (0.00%)	3 / 34 (8.82%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	1 / 7 (14.29%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Respiratory distress			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Sleep apnoea syndrome			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Wheezing			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 7 (14.29%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Delirium			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	1 / 7 (14.29%)	11 / 34 (32.35%)	5 / 18 (27.78%)
occurrences (all)	1	12	5

Mood swings			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Phonophobia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Restlessness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Amylase increased			
subjects affected / exposed	0 / 7 (0.00%)	3 / 34 (8.82%)	1 / 18 (5.56%)
occurrences (all)	0	3	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	3 / 34 (8.82%)	1 / 18 (5.56%)
occurrences (all)	0	3	1
Blood glucose increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Blood phosphorus decreased			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Blood phosphorus increased			

subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
C-reactive protein increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Cardiac murmur			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Cytomegalovirus test positive			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Drug level decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Electrocardiogram ST segment abnormal			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram T wave abnormal			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	1 / 18 (5.56%)
occurrences (all)	0	2	1
Haemoglobin decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Heart rate irregular			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Lipase increased			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Polyomavirus test positive			

subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Vitamin D decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	1 / 7 (14.29%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Weight increased			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	1 / 18 (5.56%)
occurrences (all)	0	2	1
White blood cell count decreased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
White blood cell count increased			
subjects affected / exposed	0 / 7 (0.00%)	3 / 34 (8.82%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Arterial injury			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Arteriovenous fistula site complication			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Arthropod bite			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Complications of transplant surgery			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Complications of transplanted kidney			

subjects affected / exposed	0 / 7 (0.00%)	3 / 34 (8.82%)	2 / 18 (11.11%)
occurrences (all)	0	6	2
Delayed graft function			
subjects affected / exposed	0 / 7 (0.00%)	3 / 34 (8.82%)	3 / 18 (16.67%)
occurrences (all)	0	3	3
Fall			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Graft complication			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Incision site complication			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Incision site erythema			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Incision site haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Incision site pain			
subjects affected / exposed	3 / 7 (42.86%)	6 / 34 (17.65%)	2 / 18 (11.11%)
occurrences (all)	3	6	2
Incisional hernia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Joint injury			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Lip injury			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Post procedural complication			

subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Post procedural swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Postoperative wound complication			
subjects affected / exposed	0 / 7 (0.00%)	5 / 34 (14.71%)	1 / 18 (5.56%)
occurrences (all)	0	6	1
Procedural pain			
subjects affected / exposed	0 / 7 (0.00%)	3 / 34 (8.82%)	6 / 18 (33.33%)
occurrences (all)	0	3	8
Radius fracture			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Seroma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Transplant dysfunction			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	3 / 18 (16.67%)
occurrences (all)	0	2	3
Wound complication			
subjects affected / exposed	0 / 7 (0.00%)	11 / 34 (32.35%)	8 / 18 (44.44%)
occurrences (all)	0	11	8
Wound dehiscence			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Wound haematoma			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Congenital, familial and genetic disorders			
Hydrocele			

subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Arrhythmia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	1 / 18 (5.56%)
occurrences (all)	0	2	1
Atrial fibrillation			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	1 / 18 (5.56%)
occurrences (all)	0	2	2
Bradycardia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Extrasystoles			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Myocardial infarction			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Palpitations			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Sinus tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Tachycardia			
subjects affected / exposed	2 / 7 (28.57%)	4 / 34 (11.76%)	1 / 18 (5.56%)
occurrences (all)	2	4	1
Tricuspid valve incompetence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Nervous system disorders			
Ataxia			

subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Burning sensation			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	1 / 7 (14.29%)	2 / 34 (5.88%)	3 / 18 (16.67%)
occurrences (all)	1	2	3
Dizziness postural			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Headache			
subjects affected / exposed	1 / 7 (14.29%)	6 / 34 (17.65%)	4 / 18 (22.22%)
occurrences (all)	1	7	4
Hypoaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Migraine			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	1	0	1
Peroneal nerve palsy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Polyneuropathy			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	2 / 7 (28.57%)	3 / 34 (8.82%)	6 / 18 (33.33%)
occurrences (all)	2	3	8
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 7 (14.29%)	3 / 34 (8.82%)	4 / 18 (22.22%)
occurrences (all)	1	3	4

Iron deficiency anaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Leukocytosis			
subjects affected / exposed	1 / 7 (14.29%)	3 / 34 (8.82%)	2 / 18 (11.11%)
occurrences (all)	1	4	2
Leukopenia			
subjects affected / exposed	1 / 7 (14.29%)	13 / 34 (38.24%)	3 / 18 (16.67%)
occurrences (all)	1	18	3
Lymphopenia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Microcytic anaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Nephrogenic anaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	2 / 18 (11.11%)
occurrences (all)	0	1	2
Normocytic anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Pancytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Polycythaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Thrombocytosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0

Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Vertigo			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Chalazion			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Dry eye			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Eye movement disorder			
subjects affected / exposed	2 / 7 (28.57%)	0 / 34 (0.00%)	0 / 18 (0.00%)
occurrences (all)	2	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Retinal vein occlusion			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Abdominal distension			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	1 / 7 (14.29%)	3 / 34 (8.82%)	3 / 18 (16.67%)
occurrences (all)	1	3	3
Abdominal pain lower			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Abdominal pain upper			

subjects affected / exposed	0 / 7 (0.00%)	5 / 34 (14.71%)	0 / 18 (0.00%)
occurrences (all)	0	6	0
Anal fissure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Aphthous ulcer			
subjects affected / exposed	1 / 7 (14.29%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Colitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	1 / 7 (14.29%)	14 / 34 (41.18%)	8 / 18 (44.44%)
occurrences (all)	1	17	8
Diarrhoea			
subjects affected / exposed	2 / 7 (28.57%)	8 / 34 (23.53%)	10 / 18 (55.56%)
occurrences (all)	2	9	15
Duodenogastric reflux			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	2 / 7 (28.57%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	3	1	1
Dysphagia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	2 / 18 (11.11%)
occurrences (all)	0	1	2
Gastric polyps			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Gastritis haemorrhagic			

subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Gingival pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Gingival recession			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Gingival swelling			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Haemorrhoids			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	2 / 18 (11.11%)
occurrences (all)	0	1	2
Ileus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Inguinal hernia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Mouth ulceration			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Nausea			
subjects affected / exposed	4 / 7 (57.14%)	10 / 34 (29.41%)	9 / 18 (50.00%)
occurrences (all)	4	10	13
Odynophagia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Oesophagitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Paraesthesia oral			
subjects affected / exposed	1 / 7 (14.29%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Stomatitis			

subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	3
Tongue discomfort			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	3 / 7 (42.86%)	8 / 34 (23.53%)	4 / 18 (22.22%)
occurrences (all)	3	8	5
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hepatitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Hepatomegaly			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Alopecia			
subjects affected / exposed	1 / 7 (14.29%)	2 / 34 (5.88%)	2 / 18 (11.11%)
occurrences (all)	1	2	2
Decubitus ulcer			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Dermatitis			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)	3 / 34 (8.82%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Lipohypertrophy			

subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	1 / 18 (5.56%)
occurrences (all)	0	2	1
Pityriasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	2 / 18 (11.11%)
occurrences (all)	0	1	2
Rash			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	3 / 18 (16.67%)
occurrences (all)	0	0	3
Skin lesion			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Bladder pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Bladder spasm			
subjects affected / exposed	0 / 7 (0.00%)	3 / 34 (8.82%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Chronic kidney disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	1 / 7 (14.29%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	2 / 18 (11.11%)
occurrences (all)	0	1	2

Leukocyturia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Micturition urgency			
subjects affected / exposed	1 / 7 (14.29%)	0 / 34 (0.00%)	0 / 18 (0.00%)
occurrences (all)	1	0	0
Nocturia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	1	1	0
Perinephric collection			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Perinephric oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Polyuria			
subjects affected / exposed	0 / 7 (0.00%)	5 / 34 (14.71%)	0 / 18 (0.00%)
occurrences (all)	0	5	0
Proteinuria			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	1 / 18 (5.56%)
occurrences (all)	0	3	2
Renal impairment			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	3
Renal tubular acidosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Renal tubular injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Renal tubular necrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Sterile pyuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1

Tubulointerstitial nephritis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Urethral pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Urinary incontinence			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	2 / 18 (11.11%)
occurrences (all)	0	1	2
Urinary retention			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Urinary tract disorder			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Urinary tract obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Endocrine disorders			
Hyperparathyroidism			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Hyperparathyroidism secondary			
subjects affected / exposed	2 / 7 (28.57%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	2	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	5 / 34 (14.71%)	1 / 18 (5.56%)
occurrences (all)	0	5	1
Bursitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Flank pain			

subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Groin pain			
subjects affected / exposed	1 / 7 (14.29%)	3 / 34 (8.82%)	1 / 18 (5.56%)
occurrences (all)	1	5	2
Hypercreatinaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Joint effusion			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	1 / 7 (14.29%)	6 / 34 (17.65%)	1 / 18 (5.56%)
occurrences (all)	1	8	1
Muscle twitching			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 7 (0.00%)	4 / 34 (11.76%)	0 / 18 (0.00%)
occurrences (all)	0	4	0
Neck pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Osteochondrosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	2 / 18 (11.11%)
occurrences (all)	0	3	4
Pain in jaw			

subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
BK virus infection			
subjects affected / exposed	3 / 7 (42.86%)	10 / 34 (29.41%)	6 / 18 (33.33%)
occurrences (all)	3	14	7
Bronchitis			
subjects affected / exposed	0 / 7 (0.00%)	4 / 34 (11.76%)	0 / 18 (0.00%)
occurrences (all)	0	4	0
Conjunctivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Cytomegalovirus infection			
subjects affected / exposed	0 / 7 (0.00%)	6 / 34 (17.65%)	2 / 18 (11.11%)
occurrences (all)	0	7	2
Cytomegalovirus viraemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Diarrhoea infectious			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Epstein-Barr virus infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Folliculitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Fungal skin infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Gastroenteritis			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	0 / 18 (0.00%)
occurrences (all)	0	3	0

Gastroenteritis Escherichia coli			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Gastroenteritis viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Gastrointestinal infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Herpes zoster			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Human polyomavirus infection			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	0 / 18 (0.00%)
occurrences (all)	0	3	0
Infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Influenza			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	1 / 18 (5.56%)
occurrences (all)	0	2	1
Laryngitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Latent tuberculosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Lung infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Mucocutaneous candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1

Nasopharyngitis			
subjects affected / exposed	1 / 7 (14.29%)	10 / 34 (29.41%)	4 / 18 (22.22%)
occurrences (all)	1	13	5
Oral candidiasis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Oral infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Otitis media			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Polyomavirus-associated nephropathy			
subjects affected / exposed	0 / 7 (0.00%)	3 / 34 (8.82%)	1 / 18 (5.56%)
occurrences (all)	0	3	2
Pyelonephritis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Pyuria			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Respiratory tract infection			

subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Rhinitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Skin infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	2
Soft tissue infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Subcutaneous abscess			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Tinea versicolour			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Tooth infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Tracheobronchitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	0 / 18 (0.00%)
occurrences (all)	0	2	0
Urinary tract infection			
subjects affected / exposed	1 / 7 (14.29%)	8 / 34 (23.53%)	7 / 18 (38.89%)
occurrences (all)	1	9	9
Urinary tract infection viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Viral infection			

subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Wound infection bacterial			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 7 (0.00%)	4 / 34 (11.76%)	1 / 18 (5.56%)
occurrences (all)	0	4	1
Diabetes mellitus			
subjects affected / exposed	0 / 7 (0.00%)	3 / 34 (8.82%)	3 / 18 (16.67%)
occurrences (all)	0	3	3
Dyslipidaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Fluid overload			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	1 / 18 (5.56%)
occurrences (all)	0	1	1
Folate deficiency			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hypercalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	2 / 34 (5.88%)	1 / 18 (5.56%)
occurrences (all)	0	2	1
Hypercholesterolaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	2 / 18 (11.11%)
occurrences (all)	0	1	2
Hyperglycaemia			
subjects affected / exposed	3 / 7 (42.86%)	4 / 34 (11.76%)	4 / 18 (22.22%)
occurrences (all)	3	4	4
Hyperkalaemia			
subjects affected / exposed	1 / 7 (14.29%)	9 / 34 (26.47%)	5 / 18 (27.78%)
occurrences (all)	1	14	6
Hyperlipidaemia			
subjects affected / exposed	1 / 7 (14.29%)	2 / 34 (5.88%)	1 / 18 (5.56%)
occurrences (all)	1	2	1

Hyperphosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	1 / 18 (5.56%)
occurrences (all)	0	0	1
Hypertriglyceridaemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Hyperuricaemia			
subjects affected / exposed	0 / 7 (0.00%)	4 / 34 (11.76%)	1 / 18 (5.56%)
occurrences (all)	0	4	1
Hypervolaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 34 (0.00%)	2 / 18 (11.11%)
occurrences (all)	0	0	2
Hypocalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	4 / 34 (11.76%)	1 / 18 (5.56%)
occurrences (all)	0	4	1
Hypokalaemia			
subjects affected / exposed	1 / 7 (14.29%)	6 / 34 (17.65%)	5 / 18 (27.78%)
occurrences (all)	1	8	5
Hypomagnesaemia			
subjects affected / exposed	2 / 7 (28.57%)	0 / 34 (0.00%)	3 / 18 (16.67%)
occurrences (all)	2	0	3
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)	3 / 34 (8.82%)	1 / 18 (5.56%)
occurrences (all)	0	3	1
Hypophosphataemia			
subjects affected / exposed	5 / 7 (71.43%)	11 / 34 (32.35%)	5 / 18 (27.78%)
occurrences (all)	5	12	5
Increased appetite			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Magnesium deficiency			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	0 / 18 (0.00%)
occurrences (all)	0	1	0
Metabolic acidosis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 34 (2.94%)	2 / 18 (11.11%)
occurrences (all)	0	1	2

Vitamin D deficiency			
subjects affected / exposed	2 / 7 (28.57%)	2 / 34 (5.88%)	1 / 18 (5.56%)
occurrences (all)	2	2	1

Non-serious adverse events	Total		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	58 / 59 (98.31%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Haematoma			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Hot flush			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Hypertension			
subjects affected / exposed	20 / 59 (33.90%)		
occurrences (all)	21		
Hypotension			
subjects affected / exposed	5 / 59 (8.47%)		
occurrences (all)	5		
Lymphocele			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Orthostatic hypotension			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Poor venous access			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
General disorders and administration			

site conditions				
Asthenia				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Catheter site pain				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Chills				
subjects affected / exposed	3 / 59 (5.08%)			
occurrences (all)	3			
Cyst				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Fatigue				
subjects affected / exposed	11 / 59 (18.64%)			
occurrences (all)	11			
Generalised oedema				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Impaired healing				
subjects affected / exposed	3 / 59 (5.08%)			
occurrences (all)	3			
Influenza like illness				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Infusion site swelling				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Malaise				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Oedema peripheral				
subjects affected / exposed	15 / 59 (25.42%)			
occurrences (all)	22			
Pain				

subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Peripheral swelling			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	3		
Secretion discharge			
subjects affected / exposed	3 / 59 (5.08%)		
occurrences (all)	3		
Swelling			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Kidney transplant rejection			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Dysmenorrhoea			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Erectile dysfunction			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Menorrhagia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Penile oedema			

subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Penile pain			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Prostatomegaly			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Scrotal swelling			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Vulvovaginal pain			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	12 / 59 (20.34%)		
occurrences (all)	15		
Dyspnoea			
subjects affected / exposed	8 / 59 (13.56%)		
occurrences (all)	9		
Dyspnoea exertional			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Lung infiltration			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Nasal congestion			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Oropharyngeal pain			
subjects affected / exposed	3 / 59 (5.08%)		
occurrences (all)	3		
Pleural effusion			

subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Productive cough			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Respiratory distress			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Sleep apnoea syndrome			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Wheezing			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Delirium			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	17 / 59 (28.81%)		
occurrences (all)	18		
Mood swings			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Phonophobia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Restlessness			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Amylase increased			
subjects affected / exposed	4 / 59 (6.78%)		
occurrences (all)	4		
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Blood creatinine increased			
subjects affected / exposed	4 / 59 (6.78%)		
occurrences (all)	4		
Blood glucose increased			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Blood lactate dehydrogenase increased			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Blood phosphorus decreased			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Blood phosphorus increased			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
C-reactive protein increased			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Cardiac murmur			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Cytomegalovirus test positive			

subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Drug level decreased				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Electrocardiogram ST segment abnormal				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Electrocardiogram T wave abnormal				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Gamma-glutamyltransferase increased				
subjects affected / exposed	3 / 59 (5.08%)			
occurrences (all)	3			
Haemoglobin decreased				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Heart rate irregular				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Lipase increased				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Polyomavirus test positive				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Vitamin D decreased				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Weight decreased				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Weight increased				

subjects affected / exposed	3 / 59 (5.08%)		
occurrences (all)	3		
White blood cell count decreased			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
White blood cell count increased			
subjects affected / exposed	3 / 59 (5.08%)		
occurrences (all)	3		
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Arterial injury			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Arteriovenous fistula site complication			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Arthropod bite			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Complications of transplant surgery			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Complications of transplanted kidney			
subjects affected / exposed	5 / 59 (8.47%)		
occurrences (all)	8		
Delayed graft function			
subjects affected / exposed	6 / 59 (10.17%)		
occurrences (all)	6		
Fall			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Graft complication			

subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Incision site complication				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Incision site erythema				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Incision site haemorrhage				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Incision site pain				
subjects affected / exposed	11 / 59 (18.64%)			
occurrences (all)	11			
Incisional hernia				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Joint injury				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Ligament sprain				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Lip injury				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	2			
Post procedural complication				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Post procedural haemorrhage				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Post procedural swelling				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Postoperative wound complication				

subjects affected / exposed	6 / 59 (10.17%)		
occurrences (all)	7		
Procedural pain			
subjects affected / exposed	9 / 59 (15.25%)		
occurrences (all)	11		
Radius fracture			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Seroma			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Transplant dysfunction			
subjects affected / exposed	5 / 59 (8.47%)		
occurrences (all)	5		
Wound complication			
subjects affected / exposed	19 / 59 (32.20%)		
occurrences (all)	19		
Wound dehiscence			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Wound haematoma			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Congenital, familial and genetic disorders			
Hydrocele			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Arrhythmia			
subjects affected / exposed	3 / 59 (5.08%)		
occurrences (all)	3		
Atrial fibrillation			

subjects affected / exposed	3 / 59 (5.08%)		
occurrences (all)	4		
Bradycardia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Extrasystoles			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Myocardial infarction			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Palpitations			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Sinus tachycardia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	2		
Tachycardia			
subjects affected / exposed	7 / 59 (11.86%)		
occurrences (all)	7		
Tricuspid valve incompetence			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Nervous system disorders			
Ataxia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Burning sensation			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Dizziness			
subjects affected / exposed	6 / 59 (10.17%)		
occurrences (all)	6		
Dizziness postural			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		

Headache				
subjects affected / exposed	11 / 59 (18.64%)			
occurrences (all)	12			
Hypoaesthesia				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Migraine				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Paraesthesia				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Peroneal nerve palsy				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Polyneuropathy				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Tremor				
subjects affected / exposed	11 / 59 (18.64%)			
occurrences (all)	13			
Blood and lymphatic system disorders				
Anaemia				
subjects affected / exposed	8 / 59 (13.56%)			
occurrences (all)	8			
Iron deficiency anaemia				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Leukocytosis				
subjects affected / exposed	6 / 59 (10.17%)			
occurrences (all)	7			
Leukopenia				
subjects affected / exposed	17 / 59 (28.81%)			
occurrences (all)	22			
Lymphopenia				

subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Microcytic anaemia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Nephrogenic anaemia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Neutropenia			
subjects affected / exposed	3 / 59 (5.08%)		
occurrences (all)	3		
Normocytic anaemia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Pancytopenia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Polycythaemia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Thrombocytopenia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Thrombocytosis			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Ear and labyrinth disorders			
Ear discomfort			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Vertigo			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Eye disorders			
Chalazion			

subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Dry eye			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Eye movement disorder			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Ocular hyperaemia			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Retinal vein occlusion			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Abdominal distension			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Abdominal pain			
subjects affected / exposed	7 / 59 (11.86%)		
occurrences (all)	7		
Abdominal pain lower			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Abdominal pain upper			
subjects affected / exposed	5 / 59 (8.47%)		
occurrences (all)	6		
Anal fissure			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Aphthous ulcer			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		

Colitis				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Constipation				
subjects affected / exposed	23 / 59 (38.98%)			
occurrences (all)	26			
Diarrhoea				
subjects affected / exposed	20 / 59 (33.90%)			
occurrences (all)	26			
Duodenogastric reflux				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Dyspepsia				
subjects affected / exposed	4 / 59 (6.78%)			
occurrences (all)	5			
Dysphagia				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Flatulence				
subjects affected / exposed	3 / 59 (5.08%)			
occurrences (all)	3			
Gastric polyps				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Gastritis				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Gastritis haemorrhagic				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Gingival pain				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Gingival recession				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			

Gingival swelling				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Haemorrhoids				
subjects affected / exposed	3 / 59 (5.08%)			
occurrences (all)	3			
Ileus				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Inguinal hernia				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	2			
Mouth ulceration				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	2			
Nausea				
subjects affected / exposed	23 / 59 (38.98%)			
occurrences (all)	27			
Odynophagia				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Oesophagitis				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Paraesthesia oral				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Stomatitis				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	3			
Tongue discomfort				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Vomiting				
subjects affected / exposed	15 / 59 (25.42%)			
occurrences (all)	16			

Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Hepatitis			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Hepatomegaly			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Alopecia			
subjects affected / exposed	5 / 59 (8.47%)		
occurrences (all)	5		
Decubitus ulcer			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Dermatitis			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Hyperhidrosis			
subjects affected / exposed	3 / 59 (5.08%)		
occurrences (all)	3		
Lipohypertrophy			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Night sweats			
subjects affected / exposed	3 / 59 (5.08%)		
occurrences (all)	3		
Pityriasis			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Pruritus			

subjects affected / exposed	3 / 59 (5.08%)		
occurrences (all)	3		
Rash			
subjects affected / exposed	3 / 59 (5.08%)		
occurrences (all)	3		
Skin lesion			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Urticaria			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Renal and urinary disorders			
Bladder pain			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Bladder spasm			
subjects affected / exposed	3 / 59 (5.08%)		
occurrences (all)	3		
Chronic kidney disease			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Dysuria			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Haematuria			
subjects affected / exposed	3 / 59 (5.08%)		
occurrences (all)	3		
Leukocyturia			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Micturition urgency			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Nocturia			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		

Perinephric collection				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Perinephric oedema				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Polyuria				
subjects affected / exposed	5 / 59 (8.47%)			
occurrences (all)	5			
Proteinuria				
subjects affected / exposed	3 / 59 (5.08%)			
occurrences (all)	5			
Renal impairment				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	3			
Renal tubular acidosis				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Renal tubular injury				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Renal tubular necrosis				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Sterile pyuria				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Tubulointerstitial nephritis				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Urethral pain				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Urinary incontinence				
subjects affected / exposed	3 / 59 (5.08%)			
occurrences (all)	3			

Urinary retention subjects affected / exposed occurrences (all)	1 / 59 (1.69%) 1		
Urinary tract disorder subjects affected / exposed occurrences (all)	1 / 59 (1.69%) 1		
Urinary tract obstruction subjects affected / exposed occurrences (all)	1 / 59 (1.69%) 1		
Endocrine disorders Hyperparathyroidism subjects affected / exposed occurrences (all)	1 / 59 (1.69%) 1		
Hyperparathyroidism secondary subjects affected / exposed occurrences (all)	3 / 59 (5.08%) 3		
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	2 / 59 (3.39%) 2		
Back pain subjects affected / exposed occurrences (all)	6 / 59 (10.17%) 6		
Bursitis subjects affected / exposed occurrences (all)	1 / 59 (1.69%) 1		
Flank pain subjects affected / exposed occurrences (all)	1 / 59 (1.69%) 1		
Groin pain subjects affected / exposed occurrences (all)	5 / 59 (8.47%) 8		
Hypercreatinaemia subjects affected / exposed occurrences (all)	1 / 59 (1.69%) 1		
Joint effusion			

subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Muscle spasms			
subjects affected / exposed	8 / 59 (13.56%)		
occurrences (all)	10		
Muscle twitching			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Muscular weakness			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Musculoskeletal discomfort			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Myalgia			
subjects affected / exposed	4 / 59 (6.78%)		
occurrences (all)	4		
Neck pain			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Osteochondrosis			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Pain in extremity			
subjects affected / exposed	4 / 59 (6.78%)		
occurrences (all)	7		
Pain in jaw			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
BK virus infection			
subjects affected / exposed	19 / 59 (32.20%)		
occurrences (all)	24		

Bronchitis				
subjects affected / exposed	4 / 59 (6.78%)			
occurrences (all)	4			
Conjunctivitis				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Cytomegalovirus infection				
subjects affected / exposed	8 / 59 (13.56%)			
occurrences (all)	9			
Cytomegalovirus viraemia				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Diarrhoea infectious				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	2			
Epstein-Barr virus infection				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Folliculitis				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Fungal skin infection				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Gastroenteritis				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	3			
Gastroenteritis Escherichia coli				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Gastroenteritis norovirus				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Gastroenteritis viral				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			

Gastrointestinal infection				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Herpes zoster				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	3			
Human polyomavirus infection				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	3			
Infection				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Influenza				
subjects affected / exposed	3 / 59 (5.08%)			
occurrences (all)	3			
Laryngitis				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Latent tuberculosis				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Lung infection				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Mucocutaneous candidiasis				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Nasopharyngitis				
subjects affected / exposed	15 / 59 (25.42%)			
occurrences (all)	19			
Oral candidiasis				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Oral herpes				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			

Oral infection				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Otitis media				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Pharyngitis streptococcal				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Pneumocystis jirovecii pneumonia				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	2			
Pneumonia				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Polyomavirus-associated nephropathy				
subjects affected / exposed	4 / 59 (6.78%)			
occurrences (all)	5			
Pyelonephritis				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Pyuria				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Respiratory tract infection				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Rhinitis				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Sinusitis				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Skin infection				

subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	3		
Soft tissue infection			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Subcutaneous abscess			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Tinea versicolour			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Tooth infection			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Tracheobronchitis			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Upper respiratory tract infection			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Urinary tract infection			
subjects affected / exposed	16 / 59 (27.12%)		
occurrences (all)	19		
Urinary tract infection viral			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Viral infection			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Wound infection bacterial			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	5 / 59 (8.47%)		
occurrences (all)	5		

Diabetes mellitus				
subjects affected / exposed	6 / 59 (10.17%)			
occurrences (all)	6			
Dyslipidaemia				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Fluid overload				
subjects affected / exposed	2 / 59 (3.39%)			
occurrences (all)	2			
Folate deficiency				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Hypercalcaemia				
subjects affected / exposed	3 / 59 (5.08%)			
occurrences (all)	3			
Hypercholesterolaemia				
subjects affected / exposed	3 / 59 (5.08%)			
occurrences (all)	3			
Hyperglycaemia				
subjects affected / exposed	11 / 59 (18.64%)			
occurrences (all)	11			
Hyperkalaemia				
subjects affected / exposed	15 / 59 (25.42%)			
occurrences (all)	21			
Hyperlipidaemia				
subjects affected / exposed	4 / 59 (6.78%)			
occurrences (all)	4			
Hyperphosphataemia				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Hypertriglyceridaemia				
subjects affected / exposed	1 / 59 (1.69%)			
occurrences (all)	1			
Hyperuricaemia				
subjects affected / exposed	5 / 59 (8.47%)			
occurrences (all)	5			

Hypervolaemia			
subjects affected / exposed	2 / 59 (3.39%)		
occurrences (all)	2		
Hypocalcaemia			
subjects affected / exposed	5 / 59 (8.47%)		
occurrences (all)	5		
Hypokalaemia			
subjects affected / exposed	12 / 59 (20.34%)		
occurrences (all)	14		
Hypomagnesaemia			
subjects affected / exposed	5 / 59 (8.47%)		
occurrences (all)	5		
Hyponatraemia			
subjects affected / exposed	4 / 59 (6.78%)		
occurrences (all)	4		
Hypophosphataemia			
subjects affected / exposed	21 / 59 (35.59%)		
occurrences (all)	22		
Increased appetite			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Magnesium deficiency			
subjects affected / exposed	1 / 59 (1.69%)		
occurrences (all)	1		
Metabolic acidosis			
subjects affected / exposed	3 / 59 (5.08%)		
occurrences (all)	3		
Vitamin D deficiency			
subjects affected / exposed	5 / 59 (8.47%)		
occurrences (all)	5		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
07 July 2015	Removal of the 3 mg/kg CFZ533 SC arm (former treatment arm 2A) and introduction of a more frequent dosing regimen during the first 2 months in the 10 mg/kg CFZ533 intravenous (IV) arm in Part 2
11 April 2016	Introduction of a new CFZ533 presentation, a concentrate for solution for infusion/solution for injection (also referred to as liquid in vial in the protocol). Initially, CFZ533 was developed as a lyophilized powder for solution for infusion/injection requiring reconstitution with water for injection prior to infusion or injection.
20 September 2017	Introduced by the open-label design in Part 2, to centrally evaluate all biopsies taken for suspected rejection reactions and other kidney disease related events in an unbiased, standardized and blinded manner. The decision was taken not to pursue CFZ533 exposure-response profiling (Part 3) in the scope of the present study, but to open a separate study. Therefore, Part 3 is being removed from this study protocol and the protocol is adapted accordingly including adaptation of the statistical analysis section.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported