Clinical trial results:
A Randomized, Double-Blind, Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Moderately to Severely Active Rheumatoid Arthritis Who Have Had Limited or No Treatment with Disease-Modifying Antirheumatic Drugs

Summary

EudraCT number	2012-002324-32
Trial protocol	BE SE DE GB PT AT IT GR
Global end of trial date	26 August 2015

Results information

Result version number	v2 (current)
This version publication date	07 March 2018
First version publication date	26 March 2017
Version creation reason	• Correction of full data set Revision Required

Trial information

Trial identification

Sponsor protocol code	14062

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01711359
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Alias: I4V-MC-JADZ , Trial Number: 14062

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon - Fri 9 AM - 5 PM EST , Eli Lilly and Company, 1 877-CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST , Eli Lilly and Company, 1 877-285-4559,

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	26 August 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	26 August 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to determine whether baricitinib therapy alone is noninferior to methotrexate (MTX) therapy alone in the treatment of moderate to severe active rheumatoid arthritis (RA) in those who have had limited or no treatment with MTX and are naive to other conventional or biologic disease-modifying antirheumatic drugs (DMARDs).

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 November 2012
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	Argentina: 103
Country: Number of subjects enrolled	Austria: 3
Country: Number of subjects enrolled	Belgium: 27
Country: Number of subjects enrolled	Brazil: 20
Country: Number of subjects enrolled	Canada: 17
Country: Number of subjects enrolled	Germany: 14
Country: Number of subjects enrolled	Greece: 1
Country: Number of subjects enrolled	India: 47
Country: Number of subjects enrolled	Italy: 14
Country: Number of subjects enrolled	Japan: 104
Country: Number of subjects enrolled	Mexico: 46
Country: Number of subjects enrolled	Portugal: 3
Country: Number of subjects enrolled	Russian Federation: 36
Country: Number of subjects enrolled	South Africa: 20
Country: Number of subjects enrolled	Korea, Republic of: 7
Country: Number of subjects enrolled	Sweden: 4

Country: Number of subjects enrolled	United Kingdom: 14
Country: Number of subjects enrolled	United States: 104
Worldwide total number of subjects	584
EEA total number of subjects	80

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)	501
From 65 to 84 years	83
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

All started participants received at least one dose of study drug.

Pre-assignment

Screening details:

Participants who did not respond (nonresponders) to study drug were eligible for rescue treatment beginning at Week 24.

Nonresponders were defined as lack of improvement of at least 20% in both tender joint count and swollen joint count.

Period 1

Period 1 title	Treatment Period
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Methotrexate

Arm description:

Methotrexate (MTX) administered orally once weekly with dose ranging from 10 to 20 milligram (mg) per week through Week 52. Participants also received baricitinib placebo orally once daily. Starting at Week 24, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

All started participants received at least one dose of study drug.

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

Dosage and administration details:

Methotrexate (MTX) administered orally once weekly with dose ranging from 10 to 20 milligram (mg) per week through Week 52. Participants also received baricitinib placebo orally once daily. Starting at Week 24, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

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

Dosage and administration details:

MTX administered orally once weekly with dose ranging from 10 to 20 mg per week through Week 52. Participants received baricitinib placebo orally once daily. Starting at Week 24, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

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

Dosage and administration details:

Folic acid administered orally every day.

Arm title	Baricitinib

Arm description:

Baricitinib 4 mg administered orally once daily through Week 52. Participants received MTX placebo orally once weekly through Week 52. Starting at Week 24, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

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

Dosage and administration details:

Baricitinib 4 mg administered orally once daily through Week 52. Participants will receive MTX placebo orally once weekly through Week 52. Starting at Week 24, participants who are nonresponders will be rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

Investigational medicinal product name	Baricitinib
Investigational medicinal product code	
Other name	LY3009104
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Baricitinib 4 mg administered orally once daily through Week 52. Participants will receive MTX placebo orally once weekly through Week 52. Starting at Week 24, participants who are nonresponders will be rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

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

Dosage and administration details:

Folic acid administered orally every day.

Arm title	Baricitinib + MTX

Arm description:

Baricitinib 4 mg administered orally once daily through Week 52. Participants received MTX orally once weekly with dose ranging from 10 to 20 mg per week through Week 52. Starting at Week 24, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

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

Dosage and administration details:

Baricitinib 4 milligram (mg) administered orally once daily through Week 52. Participants will receive methotrexate (MTX) orally once weekly with dose ranging from 10 to 20 mg per week through Week 52. Starting at Week 24, participants who are nonresponders will be rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

Investigational medicinal product name	Baricitinib
Investigational medicinal product code	
Other name	LY3009104
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Baricitinib 4 milligram (mg) administered orally once daily through Week 52. Participants will receive methotrexate (MTX) orally once weekly with dose ranging from 10 to 20 mg per week through Week 52. Starting at Week 24, participants who are nonresponders will be rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

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

Dosage and administration details:

Folic acid administered orally every day.

Number of subjects in period 1	Methotrexate	Baricitinib	Baricitinib + MTX
Started	210	159	215
Rescued	26 [1]	7 [2]	6 [3]
Completed	161	136	173
Not completed	49	23	42
Adverse event, serious fatal	3	-	-
Consent withdrawn by subject	18	7	13
Physician decision	4	3	2
Adverse event, non-fatal	8	10	24
Sponsor Decision	1	-	-
Lost to follow-up	1	1	1
Entry Criteria Not Met	1	-	-
Lack of efficacy	13	2	2

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Participants who were nonresponders based on tender/swollen joint count were entered into the rescue milestone calculation.

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Participants who were nonresponders based on tender/swollen joint count were entered into the rescue milestone calculation.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Participants who were nonresponders based on tender/swollen joint count were entered into the rescue milestone calculation.

Period 2

Period 2 title	Follow Up
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Methotrexate - Follow-up

Arm description:

No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Baricitinib - Follow-up

Arm description:

No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Baricitinib + MTX - Follow-up

Arm description:

No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug. Includes participants who were rescued to Baricitinib + MTX.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2[4]	Methotrexate - Follow-up	Baricitinib - Follow-up	Baricitinib + MTX - Follow-up
Started	25	15	28
Completed	25	15	28

Notes:

[4] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Includes participants who entered the post-treatment follow-up period

Baseline characteristics

Reporting groups

Reporting group title	Methotrexate

Reporting group description:

Methotrexate (MTX) administered orally once weekly with dose ranging from 10 to 20 milligram (mg) per week through Week 52. Participants also received baricitinib placebo orally once daily. Starting at Week 24, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

All started participants received at least one dose of study drug.

Reporting group title	Baricitinib

Reporting group description:

Baricitinib 4 mg administered orally once daily through Week 52. Participants received MTX placebo orally once weekly through Week 52. Starting at Week 24, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

Reporting group title	Baricitinib + MTX

Reporting group description:

Baricitinib 4 mg administered orally once daily through Week 52. Participants received MTX orally once weekly with dose ranging from 10 to 20 mg per week through Week 52. Starting at Week 24, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

Reporting group values	Methotrexate	Baricitinib	Baricitinib + MTX
Number of subjects	210	159	215
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	50.5	50.9	48.5
standard deviation	± 13.4	± 13	± 13.5
Gender, Male/Female Units: participants			
Female	148	121	156
Male	62	38	59
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	11	10	20
Asian	60	44	61
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	10	5	10
White	128	98	123
More than one race	1	2	1
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
Argentina	41	29	33
Austria	1	1	1
Belgium	6	10	11

Brazil	8	3	9
Canada	5	5	7
Germany	5	5	4
Greece	0	0	1
India	18	12	17
Italy	8	2	4
Japan	36	29	39
Mexico	12	14	20
Portugal	1	0	2
Russian Federation	11	13	12
South Africa	7	4	9
Korea, Republic of	4	1	2
Sweden	3	0	1
United Kingdom	7	3	4
United States	37	28	39
Duration of Rheumatoid Arthritis			
Units: years			
median	0.2	0.2	0.2
inter-quartile range (Q1-Q3)	0.1 to 0.6	0.1 to 1.1	0.1 to 1
Tender Joint Count of 68 evaluable joints			
Units: number of joints			
arithmetic mean	26.5	26.4	27.7
standard deviation	± 14.8	± 14.1	± 14.5
Swollen Joint Count of 66 evaluable joints			
Units: number of joints			
arithmetic mean	16.4	16.1	16.3
standard deviation	± 10.6	± 9.2	± 9.5
High sensitivity C-reactive protein			
Units: milligrams per liter (mg/L)			
arithmetic mean	22.34	23.75	24.27
standard deviation	± 21.78	± 26.24	± 29.42

Reporting group values	Total		
Number of subjects	584		
Age categorical			
Units: Subjects			

Age Continuous			
Units: years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female			
Units: participants			
Female	425		
Male	159		
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	41		
Asian	165		

Native Hawaiian or Other Pacific Islander	0		
Black or African American	25		
White	349		
More than one race	4		
Unknown or Not Reported	0		
Region of Enrollment Units: Subjects			
Argentina	103		
Austria	3		
Belgium	27		
Brazil	20		
Canada	17		
Germany	14		
Greece	1		
India	47		
Italy	14		
Japan	104		
Mexico	46		
Portugal	3		
Russian Federation	36		
South Africa	20		
Korea, Republic of	7		
Sweden	4		
United Kingdom	14		
United States	104		
Duration of Rheumatoid Arthritis Units: years			
median			
inter-quartile range (Q1-Q3)	-		
Tender Joint Count of 68 evaluable joints Units: number of joints			
arithmetic mean			
standard deviation	-		
Swollen Joint Count of 66 evaluable joints Units: number of joints			
arithmetic mean			
standard deviation	-		
High sensitivity C-reactive protein Units: milligrams per liter (mg/L)			
arithmetic mean			
standard deviation	-		

End points

End points reporting groups

Reporting group title	Methotrexate

Reporting group description:

Methotrexate (MTX) administered orally once weekly with dose ranging from 10 to 20 milligram (mg) per week through Week 52. Participants also received baricitinib placebo orally once daily. Starting at Week 24, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

All started participants received at least one dose of study drug.

Reporting group title	Baricitinib

Reporting group description:

Baricitinib 4 mg administered orally once daily through Week 52. Participants received MTX placebo orally once weekly through Week 52. Starting at Week 24, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

Reporting group title	Baricitinib + MTX

Reporting group description:

Baricitinib 4 mg administered orally once daily through Week 52. Participants received MTX orally once weekly with dose ranging from 10 to 20 mg per week through Week 52. Starting at Week 24, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

Reporting group title	Methotrexate - Follow-up

Reporting group description:

No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug.

Reporting group title	Baricitinib - Follow-up

Reporting group description:

No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug.

Reporting group title	Baricitinib + MTX - Follow-up

Reporting group description:

No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug. Includes participants who were rescued to Baricitinib + MTX.

Subject analysis set title	Baricitinib
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All randomized participants who received at least 1 dose of study drug with evaluable PK data.

Primary: Percentage of Participants Achieving American College of Rheumatology 20% Improvement (ACR20)

End point title	Percentage of Participants Achieving American College of Rheumatology 20% Improvement (ACR20)

End point description:

ACR20 Responder Index is a composite of clinical, laboratory, and functional measures in rheumatoid arthritis (RA). "ACR20 Responder" is a participant who has at least 20% improvement in both tender and swollen joint counts and in at least 3 of the following 5 criteria: Physician's Global Assessment of Disease Activity, Patient's Global Assessment of Disease Activity using visual analog scale (VAS), Health Assessment Questionnaire-Disability Index (HAQ-DI), participant's assessment of pain, and high-sensitivity C-reactive protein (hsCRP). Participants with missing responses and participants who discontinue study or drug or are rescued before analysis time point are deemed non-responders.

Analysis Population Description: Modified Intent-to-Treat (mITT) population: all randomized participants who received at least 1 dose of study drug. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using nonresponder imputation (NRI).

End point type	Primary

End point timeframe:
Week 24

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	210	159	215	
Units: Percent of participants				
number (not applicable)				
Week 24	61.9	76.7	78.1	

Statistical analyses

Statistical analysis title	Statistical Analysis for ACR20
Comparison groups	Baricitinib v Methotrexate
Number of subjects included in analysis	369
Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
Parameter estimate	Newcombe-Wilson method
Point estimate	14.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.5
upper limit	24.1

Notes:

[1] - Noninferiority is concluded if the lower bound of the 95% CI for the difference in response rate is >-12%

Secondary: Change from Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) Score

End point title	Change from Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) Score

End point description:

HAQ-DI assesses the participant's self-perception on the degree of difficulty [0 (without any difficulty), 1 (with some difficulty), 2 (with much difficulty), and 3 (unable to do)] when dressing and grooming, arising, eating, walking, hygiene, reaching, gripping, and performing other daily activities. Scores for each functional area are averaged to calculate the HAQ-DI score, which ranges from 0 (no disability) to 3 (worst disability). A decrease in HAQ-DI score indicates an improvement in the participant's condition.

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using modified baseline observation carried forward (mBOCF).

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	210	159	215	
Units: units on a scale				
arithmetic mean (standard deviation)	-0.73 (± 0.71)	-1.01 (± 0.74)	-0.92 (± 0.74)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in the Disease Activity Score Based on a 28-Joint Count and High-sensitivity C-reactive Protein (DAS28-hsCRP)

End point title	Change From Baseline in the Disease Activity Score Based on a 28-Joint Count and High-sensitivity C-reactive Protein (DAS28-hsCRP)

End point description:

Disease Activity Score (DAS) modified to include 28 joint count (DAS28) consisted of a composite score of the following variables: tender joint count (TJC28), swollen joint count (SJC28), C-reactive protein (CRP) (milligrams per liter), and Patient's Global Assessment of Disease Activity. DAS28 was calculated using the following formula: DAS28-CRP=0.56*square root (sqrt)(TJC28)+0.28*sqrt(SJC28)+0.36*natural log(CRP+1)+0.014*Patient's Global VAS+0.96. Scores ranged 1.0-9.4, where lower scores indicated less disease activity.

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mBOCF.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	210	159	215	
Units: units on a scale				
arithmetic mean (standard deviation)	-2.01 (± 1.51)	-2.74 (± 1.39)	-2.82 (± 1.58)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the modified Total Sharp Score (mTSS)

End point title	Change from Baseline in the modified Total Sharp Score (mTSS)

End point description:

X-rays of the hands/wrists and feet were scored for structural progression as measured using the mTSS. This methodology quantified the extent of bone erosions and joint space narrowing for 44 and 42 joints, with higher scores representing greater damage. The mTSS at a time point is the sum of the erosion

(range from 0 to 280) and JSN (range from 0 to 168) scores, for a maximum score of 448.

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug and had baseline and at least 1 post-baseline assessments. Missing values due to discontinuation of study, rescue, or missing data were imputed using linear extrapolation (LE).

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	191	152	198	
Units: units on a scale				
arithmetic mean (standard deviation)	0.64 (± 1.81)	0.43 (± 1.18)	0.32 (± 1.14)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Achieved a Simplified Disease Activity Index (SDAI) Score ≤3.3

End point title	Percentage of Participants Who Achieved a Simplified Disease Activity Index (SDAI) Score ≤3.3

End point description:

SDAI is a tool for measurement of disease activity in RA that integrates TJC28, SJC28, acute phase response using C-reactive protein (milligrams per liter), Participant's Global Assessment of Disease Activity using VAS centimeters (cm), and Physician's Global Assessment of Disease Activity using VAS (cm). The SDAI is calculated by summing the values of the 5 components. Lower scores indicated less disease activity. An index-based definition of remission occurs with an SDAI score ≤3.3.

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using NRI.

End point type	Secondary

End point timeframe:

Week 24

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	210	159	215	
Units: percentage of participants				
number (not applicable)	10.5	22	22.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving American College of Rheumatology 50% (ACR50) Response

End point title	Percentage of Participants Achieving American College of Rheumatology 50% (ACR50) Response

End point description:

ACR50 Responder Index is composite of clinical, laboratory, and functional measures in RA. "ACR50 Responder" is a participant who has at least 50% improvement in both tender and swollen joint counts and in at least 3 of the following 5 criteria: Physician's Global Assessment of Disease Activity, Patient's Global Assessment of Disease Activity using visual analog scale (VAS), HAQ-DI, participant's assessment of pain, and hsCRP. Participants with missing responses and participants who discontinue study or drug or are rescued before analysis time point are deemed non-responders.

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using NRI.

End point type	Secondary

End point timeframe:

Week 12, Week 24, Week 52

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	210	159	215	
Units: Percent of participants				
number (not applicable)				
Week 12	32.9	54.7	60	
Week 24	43.3	59.7	63.3	
Week 52	37.6	57.2	61.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving American College of Rheumatology 70% (ACR70) Response

End point title	Percentage of Participants Achieving American College of Rheumatology 70% (ACR70) Response

End point description:

ACR70 Responder Index is composite of clinical, laboratory, and functional measures in RA. "ACR70 Responder" is a participant who has at least 50% improvement in both tender and swollen joint counts and in at least 3 of the following 5 criteria: Physician's Global Assessment of Disease Activity, Patient's Global Assessment of Disease Activity using visual analog scale (VAS), HAQ-DI, participant's assessment of pain, and hsCRP. Participants with missing responses and participants who discontinue study or drug or are rescued before analysis time point are deemed non-responders.

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using NRI.

End point type	Secondary

End point timeframe:
Week 12, Week 24, Week 52

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	210	159	215	
Units: Percent of participants				
number (not applicable)				
Week 12	15.7	30.8	33.5	
Week 24	21.4	42.1	39.5	
Week 52	25.2	42.1	46	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Disease Activity Index (CDAI) Score

End point title	Change from Baseline in Clinical Disease Activity Index (CDAI) Score

End point description:

The CDAI is a tool for measurement of disease activity in RA that does not require a laboratory component and was scored by the investigative site. It integrates TJC28, SJC28, Patient's Global Assessment of Disease Activity using visual analog scale (cm), and Physician's Global Assessment of Disease Activity using visual analog scale (cm). The CDAI is calculated by summing the values of the 4 components. Lower scores indicated less disease activity.

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug with a baseline value and at least 1 post baseline value. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using modified last observation carried forward (mLOCF).

End point type	Secondary

End point timeframe:
Baseline, Week 24; Baseline, Week 52

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	200	157	208	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24	-22.12 (± 16.12)	-28.2 (± 13.96)	-29.86 (± 14.05)	
Week 52	-21.95 (± 18.07)	-28.94 (± 14.58)	-30.72 (± 14.87)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Disease Activity Score 28–Erythrocyte Sedimentation Rate (DAS28-ESR)

End point title	Change From Baseline in Disease Activity Score 28–Erythrocyte Sedimentation Rate (DAS28-ESR)

End point description:

DAS28 consisted of a composite score of the following variables: tender joint count (TJC28), swollen joint count (SJC28), erythrocyte sedimentation rate (ESR) (millimeters per hour), and Patient's Global Assessment of Disease Activity. DAS28 was calculated using the following formula: DAS28-ESR=0.56*square root (sqrt)(TJC28)+0.28*sqrt(SJC28)+0.70*natural log(ESR)+0.014*Patient's Global VAS. Scores ranged 1.0-9.4, where lower scores indicated less disease activity.

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug, with a baseline value and at least 1 post baseline value. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mLOCF.

End point type	Secondary

End point timeframe:

Baseline, Week 24; Baseline, Week 52

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	203	159	209	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24	-2.2 (± 1.53)	-2.76 (± 1.45)	-3.06 (± 1.46)	
Week 52	-2.32 (± 1.77)	-2.84 (± 1.57)	-3.22 (± 1.48)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) remission

End point title	Percentage of Participants Achieving American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) remission

End point description:

The ACR/EULAR definitions of RA remission include a "Boolean-based definition". The Boolean-based definition of remission occurs when all 4 of the following criteria are met at the same visit: TJC28 ≤1, SJC28 ≤1, acute phase response using C-reactive protein (milligrams per deciliter) ≤1, Patient's Global

Assessment of Disease Activity using VAS (cm) ≤1.

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using NRI.

End point type	Secondary

End point timeframe:

Week 12, Week 24, Week 52

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	210	159	215	
Units: percentage of participants				
number (not applicable)				
Week 12	5.7	13.8	14.4	
Week 24	8.6	18.9	16.3	
Week 52	11.4	17	20.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Joint Space Narrowing and Bone Erosion Scores

End point title	Change From Baseline in Joint Space Narrowing and Bone Erosion Scores

End point description:

X-rays of the hands/wrists and feet were assessed for joint space narrowing (JSN) and bone erosions. Assessment of JSN for each hand (15 joints per hand) and foot (6 joints per foot), including subluxation, is scored from 0 to 4, with 0 indicating no (normal) JSN and 4 indicating complete loss of joint space, bony ankylosis or luxation. JSN scores ranged from 0-168. A score of 0 would indicate no change and higher scores represent a worsening of joint space narrowing. The bone erosion score is a summary of erosion severity in 32 joints of the hands and 12 joints of the feet. Each joint is scored according to the surface area involved from 0 to 5 for hand joints and 0 to 10 for the foot joints, with 0 indicating no erosion and the highest score (5 for the hand and 10 for the foot) indicating extensive loss of bone from more than one half of the articulating bone. Erosion scores ranged from 0 (no erosion) to 280 (high erosion).

Analysis Population Description: mITT population.

End point type	Secondary

End point timeframe:

Baseline, Week 24; Baseline, Week 52

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	191	152	198	
Units: units on a scale				
arithmetic mean (standard deviation)				
JSN Week 24	0.15 (± 0.94)	0.08 (± 0.44)	0.05 (± 0.44)	
JSN Week 52	0.23 (± 1)	0.26 (± 1.14)	0.08 (± 0.88)	
Bone Erosion Week 24	0.49 (± 1.14)	0.35 (± 0.92)	0.27 (± 0.95)	
Bone Erosion Week 52	0.8 (± 1.8)	0.55 (± 1.48)	0.33 (± 1.21)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Duration of Morning Joint Stiffness

End point title	Change From Baseline in Duration of Morning Joint Stiffness

End point description:

Participants reported the duration of their morning joint stiffness (MJS) in hours and minutes. The participants were asked about their duration of morning joint stiffness on the day prior to the study visit to capture actual symptoms, since the participant may have had an atypical morning routine on the day of the study visit. If morning joint stiffness duration was longer than 12 hours (720 minutes), it was truncated to 720 minutes for statistical presentations and analyses. A decrease in duration of morning joint stiffness indicated an improvement in the participant's condition.

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug, with a baseline value and at least 1 post baseline value. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mLOCF.

End point type	Secondary

End point timeframe:

Baseline, Week 52

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	204	159	209	
Units: Minutes				
median (confidence interval 95%)	-40 (-55 to -30)	-55 (-60 to -40)	-60 (-80 to -50)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Worst Tiredness Numeric Rating Scale (NRS)

End point title	Change from Baseline in Worst Tiredness Numeric Rating Scale (NRS)

End point description:

Participants rated their tiredness by selecting a number from 0 to 10 that best described their worst tiredness during the last 24 hours, where 0 represents "no tiredness" and 10 represents "as bad as you can imagine".

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug, with a baseline value and at least 1 post baseline value. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mLOCF.

End point type	Secondary

End point timeframe:

Baseline, Week 24; Baseline Week 52

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	204	159	209	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24	-2.2 (± 2.7)	-3 (± 3.1)	-3 (± 2.8)	
Week 52	-2.3 (± 2.8)	-2.9 (± 3.1)	-3 (± 2.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Worst Joint Pain Numeric Rating Scale (NRS)

End point title	Change From Baseline in Worst Joint Pain Numeric Rating Scale (NRS)

End point description:

Participants rated their joint pain by selecting a number from 0 to 10 that best described their worst joint pain during the last 24 hours, where 0 represents "no pain" and 10 represents "pain as bad as you can imagine".

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug, with a baseline value and at least 1 post baseline value.Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mLOCF.

End point type	Secondary

End point timeframe:

Baseline, Week 24; Baseline Week 52

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	204	159	209	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24	-2.8 (± 2.5)	-3.9 (± 2.7)	-3.9 (± 2.6)	
Week 52	-3 (± 2.8)	-3.9 (± 2.9)	-4.1 (± 2.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Mental Component Score (MCS) and Physical Component Score (PCS) of the Medical Outcomes Study 36-Item Short Form Health Survey Version 2 Acute (SF-36v2 Acute)

End point title	Change from Baseline in Mental Component Score (MCS) and Physical Component Score (PCS) of the Medical Outcomes Study 36-Item Short Form Health Survey Version 2 Acute (SF-36v2 Acute)

End point description:

The SF-36 is a health-related survey that assesses participant's quality of life and consists of 36 questions covering 8 health domains: physical functioning, bodily pain, role limitations due to physical problems and emotional problems, general health, mental health, social functioning, vitality, and 2 component scores (MCS and PCS). MCS consisted of social functioning, vitality, mental health, and role-emotional scales. PCS consisted of physical functioning, bodily pain, role-physical, and general health scales. Each domain is scored by summing the individual items and transforming the scores into a 0 to 100 scale with higher scores indicating better health status or functioning.

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug, with a baseline value and at least 1 post baseline value. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mLOCF.

End point type	Secondary

End point timeframe:

Baseline, Week 24; Baseline Week 52

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	202	159	207	
Units: units on a scale				
arithmetic mean (standard deviation)				
MCS Week 24	3.4 (± 10.8)	5.9 (± 11.7)	4.6 (± 11.6)	
MCS Week 52	2.4 (± 10.9)	5.8 (± 11.9)	5 (± 11.5)	
PCS Week 24	9.4 (± 9.2)	12.5 (± 9.1)	13.2 (± 9.6)	
PCS Week 52	9.4 (± 10.1)	11.6 (± 9.6)	13.3 (± 9.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in European Quality of Life–5 Dimensions–5 Level (EQ-5D-5L) scores

End point title	Change From Baseline in European Quality of Life–5 Dimensions–5 Level (EQ-5D-5L) scores

End point description:

EQ-5D-5L is a standardized measure of health status of the participant. One component consists of a descriptive system of the respondent's health comprised of the following 5 participant-reported dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems. The responses are used to derive the health state index scores using the United Kingdom (UK) algorithm, with scores ranging from -0.594 to 1, and the United States (US) algorithm, with scores ranging from -0.109 to 1. A higher score indicates better health state.

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug, with a baseline value and at least 1 post-baseline value. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mLOCF.

End point type	Secondary

End point timeframe:

Baseline, Week 24; Baseline Week 52

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	202	159	207	
Units: units on a scale				
arithmetic mean (standard deviation)				
Index Score (US Algorithm) Week 24	0.142 (± 0.189)	0.197 (± 0.164)	0.194 (± 0.18)	
Index Score (US Algorithm) Week 52	0.138 (± 0.203)	0.186 (± 0.177)	0.185 (± 0.186)	
Index Score (UK Algorithm) Week 24	0.205 (± 0.274)	0.285 (± 0.241)	0.282 (± 0.255)	
Index Score (UK Algorithm) Week 52	0.197 (± 0.294)	0.271 (± 0.258)	0.268 (± 0.266)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-F) Scores

End point title	Change From Baseline in Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-F) Scores

End point description:

The Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) Scale is a 13-item, symptom-specific questionnaire that specifically assesses the participant's self-reported severity of fatigue and its impact upon daily activities and functioning. The FACIT-F uses a numeric rating scale of 0 ("Not at all") to 4 ("Very much") for each item to assess fatigue and its impact in the past 7 days. Total scores range from 0 to 52, with higher scores indicating less fatigue.

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug, with a baseline value and at least 1 post baseline value. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mLOCF.

End point type	Secondary

End point timeframe:

Baseline, Week 24; Baseline Week 52

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	204	159	209	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 24	9.3 (± 11.2)	13 (± 10.8)	12.3 (± 11.5)	
Week 52	9.1 (± 10.9)	11.3 (± 10.8)	12.6 (± 11.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Work Productivity and Activity Impairment-Rheumatoid Arthritis (WPAI-RA) Scores

End point title	Change From Baseline in Work Productivity and Activity Impairment-Rheumatoid Arthritis (WPAI-RA) Scores

End point description:

The Work Productivity and Activity Impairment-Rheumatoid Arthritis (WPAI-RA) questionnaire was developed to measure the effect of general health and symptom severity on work productivity and regular activities in the 7 days prior to the visit. It contains 6 items covering overall work productivity (health), overall work productivity (symptom), impairment of regular activities (health), and impairment of regular activities (symptom). Scores are calculated as impairment percentages. The WPAI-RA yields four types of scores: Absenteeism (work time missed), Presenteeism (impairment at work), Work productivity loss (overall work impairment), and Activity impairment.

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug, with a baseline value and an observed value at the time point being summarized.

End point type	Secondary

End point timeframe:

Baseline, Week 24; Baseline Week 52

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	210	159	215	
Units: Percentage of Impairment				
arithmetic mean (standard deviation)				
Absenteeism Week 24 (n=76, 56, 90)	-3.6 (± 35.5)	-8.7 (± 30.4)	-7.6 (± 26.5)	
Absenteeism Week 52 (n=52, 51, 71)	-3 (± 29.2)	-8.4 (± 29.7)	-7.3 (± 21.8)	
Presenteeism Week 24 (n=70, 51, 86)	-19 (± 25)	-26 (± 27)	-32 (± 26)	
Presenteeism Week 52 (n=51, 47, 75)	-26 (± 26)	-27 (± 24)	-33 (± 25)	
Work Productivity Loss Week 24 (n=70, 71, 86)	-17.8 (± 30.2)	-25.6 (± 29.1)	-30.9 (± 29.6)	
Work Productivity Loss Week 52 (n=51, 47, 75)	-24.1 (± 30.5)	-27.6 (± 27.3)	-33.8 (± 27.5)	

Activity Impairment Week 24 (n=184, 145, 192)	-25 (± 26)	-36 (± 28)	-31 (± 28)	
Activity Impairment Week 52 (n=141, 131, 172)	-28 (± 27)	-34 (± 27)	-37 (± 27)	

Statistical analyses

No statistical analyses for this end point

Secondary: Population Pharmacokinetics (PK): Peak Concentration at Steady State (Cmax,ss) of Baricitinib

End point title	Population Pharmacokinetics (PK): Peak Concentration at Steady State (Cmax,ss) of Baricitinib

End point description:

Analysis population description: all randomized participants who received at least 1 dose of study drug with evaluable PK data.

End point type	Secondary

End point timeframe:

Week 0: 15 and 60 minutes postdose; Week 4: 2 to 4 hours post-dose; Week 8: 4 to 6 hours post-dose; Week 12; Week 24; Week 32; Pre-dose

End point values	Baricitinib			
Subject group type	Subject analysis set			
Number of subjects analysed	355			
Units: nanomole/Liter (nmol/L)				
geometric mean (geometric coefficient of variation)	135 (± 23.1)			

Statistical analyses

No statistical analyses for this end point

Secondary: Population PK: Area Under the Concentration Curve Versus Time at a Dosing Interval at Steady State (AUCtau,ss) of Baricitinib

End point title	Population PK: Area Under the Concentration Curve Versus Time at a Dosing Interval at Steady State (AUCtau,ss) of Baricitinib

End point description:

Analysis population description: all randomized participants who received at least 1 dose of study drug with evaluable PK data.

End point type	Secondary

End point timeframe:

Week 0: 15 and 60 minutes postdose; Week 4: 2 to 4 hours post-dose; Week 8: 4 to 6 hours post-dose; Week 12; Week 24; Week 32; Pre-dose

End point values	Baricitinib			
Subject group type	Subject analysis set			
Number of subjects analysed	355			
Units: nanomole/Liter (nmol/L)				
geometric mean (geometric coefficient of variation)	1280 (± 47.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in European Quality of Life-5 Dimensions-5 Level (EQ-5D-5L) Scores (Self-Perceived Health)

End point title	Change From Baseline in European Quality of Life-5 Dimensions-5 Level (EQ-5D-5L) Scores (Self-Perceived Health)

End point description:

A second component of the EQ-5D-5L is a self-perceived health score which is assessed using a VAS that ranges from 0 to 100 millimeter (mm), where 0 indicates the worst health you can imagine and 100 indicates the best health you can imagine.

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug, with a baseline value and at least 1 post baseline value. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mLOCF.

End point type	Secondary

End point timeframe:

Baseline, Week 24; Baseline Week 52

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	202	159	207	
Units: millimeter(s)				
arithmetic mean (standard deviation)				
Self-Perceived Health (Week 24)	14.5 (± 28.3)	24.1 (± 26)	21.4 (± 31.4)	
Self-Perceived Health (Week 52)	13.6 (± 30.1)	24.5 (± 28.7)	24.5 (± 30.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving American College of Rheumatology 20% Improvement (ACR20)

End point title	Percentage of Participants Achieving American College of

	Rheumatology 20% Improvement (ACR20)

End point description:

ACR20 Responder Index is a composite of clinical, laboratory, and functional measures in rheumatoid arthritis (RA). "ACR20 Responder" is a participant who has at least 20% improvement in both tender and swollen joint counts and in at least 3 of the following 5 criteria: Physician's Global Assessment of Disease Activity, Patient's Global Assessment of Disease Activity using visual analog scale (VAS), Health Assessment Questionnaire-Disability Index (HAQ-DI), pain due to arthritis, and high-sensitivity C-reactive protein (hsCRP). Participants with missing responses and participants who discontinue study or drug or are rescued before analysis time point are deemed non-responders.
Analysis Population Description: Modified Intent-to-Treat (mITT) population: all randomized participants who received at least 1 dose of study drug. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using nonresponder imputation (NRI).

End point type	Secondary

End point timeframe:

Week 52

End point values	Methotrexate	Baricitinib	Baricitinib + MTX	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	210	159	215	
Units: Percent of participants				
number (not applicable)	55.7	73	72.6	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All enrolled participants including those receiving rescue therapy, with events occurring after rescue accounted separately. Rescue therapy occurred at Week 24 or later, if determined to be nonresponders.

Adverse event reporting additional description:

I4V-MC-JADZ

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.0

Reporting groups

Reporting group title	Baricitinib

Reporting group description:

Baricitinib 4 mg administered orally once daily through Week 52. Participants received MTX placebo orally once weekly through Week 52. Starting at Week 24, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

Reporting group title	Baricitinib + MTX

Reporting group description:

Baricitinib 4 mg administered orally once daily through Week 52. Participants received MTX orally once weekly with dose ranging from 10 to 20 mg per week through Week 52. Starting at Week 24, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

Reporting group title	Methotrexate

Reporting group description:

Methotrexate (MTX) administered orally once weekly with dose ranging from 10 to 20 milligram (mg) per week through Week 52. Participants also received baricitinib placebo orally once daily. Starting at Week 24, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily and MTX orally once weekly.

Reporting group title	Rescue

Reporting group description:

Baricitinib 4 mg administered orally once daily through Week 52. Participants received MTX orally once weekly with dose ranging from 10 to 20 mg per week through Week 52.

Reporting group title	Baricitinib - Follow-up

Reporting group description:

No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug.

Reporting group title	Methotrexate - Follow-up

Reporting group description:

No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug.

Reporting group title	Baricitinib + MTX - Follow-up

Reporting group description:

No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug. Includes participants who were rescued to Baricitinib + MTX.

Serious adverse events	Baricitinib	Baricitinib + MTX	Methotrexate
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 159 (7.55%)	17 / 215 (7.91%)	20 / 210 (9.52%)
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)			
cervix carcinoma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[1]	1 / 121 (0.83%)	0 / 156 (0.00%)	0 / 148 (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
gallbladder adenosquamous carcinoma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (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
malignant melanoma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (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
General disorders and administration site conditions			
drowning			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
fatigue			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	0 / 215 (0.00%)	0 / 210 (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
non-cardiac chest pain			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oedema peripheral			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (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
Reproductive system and breast disorders			
genital prolapse			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (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
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumothorax spontaneous			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (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
pulmonary embolism			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
pulmonary fibrosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Investigations			
lymphocyte count decreased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (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
Injury, poisoning and procedural complications			
fall			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	2 / 210 (0.95%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
overdose			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (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
spinal compression fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	2 / 210 (0.95%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
toxicity to various agents			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (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
wrist fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery disease			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	1 / 159 (0.63%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (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
Nervous system disorders			
cerebral haemorrhage			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (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
migraine			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (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
Eye disorders			
cataract			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
chronic gastritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (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
duodenal ulcer			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	0 / 215 (0.00%)	0 / 210 (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
enterocolitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (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
gastric ulcer haemorrhage			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
umbilical hernia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
rheumatoid arthritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	1 / 210 (0.48%)
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			
acute hepatitis b			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (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
bronchitis haemophilus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	0 / 215 (0.00%)	0 / 210 (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
campylobacter gastroenteritis			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (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
cellulitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	0 / 215 (0.00%)	0 / 210 (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
escherichia sepsis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	0 / 215 (0.00%)	2 / 210 (0.95%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infectious colitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	0 / 215 (0.00%)	0 / 210 (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
lung infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

meningitis bacterial			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumocystis jirovecii pneumonia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (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
pneumonia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	1 / 215 (0.47%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	1 / 1	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis acute			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	1 / 215 (0.47%)	0 / 210 (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
sepsis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	0 / 215 (0.00%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	1 / 210 (0.48%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Rescue	Baricitinib - Follow-up	Methotrexate - Follow-up
Total subjects affected by serious adverse events			

subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
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)			
cervix carcinoma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[1]	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gallbladder adenosquamous carcinoma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
malignant melanoma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
drowning			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fatigue			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oedema peripheral			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
genital prolapse			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumothorax spontaneous			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary fibrosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
lymphocyte count decreased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
fall			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
overdose			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal compression fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
toxicity to various agents			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wrist fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (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
coronary artery disease			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial ischaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebral haemorrhage			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
migraine			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
cataract			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
chronic gastritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenal ulcer			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
enterocolitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric ulcer haemorrhage			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
umbilical hernia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
rheumatoid arthritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
acute hepatitis b			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis haemophilus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
campylobacter gastroenteritis			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
escherichia sepsis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infectious colitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

meningitis bacterial			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumocystis jirovecii pneumonia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis acute			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Baricitinib + MTX - Follow-up		
Total subjects affected by serious adverse events			

subjects affected / exposed	0 / 28 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
cervix carcinoma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[1]	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
gallbladder adenosquamous carcinoma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
malignant melanoma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
drowning			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
fatigue			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
non-cardiac chest pain			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
oedema peripheral			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pyrexia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
genital prolapse			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pneumothorax spontaneous			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pulmonary embolism			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pulmonary fibrosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
lymphocyte count decreased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
fall			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
femur fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
overdose			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
spinal compression fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
tibia fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
toxicity to various agents			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
wrist fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
atrial fibrillation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
coronary artery disease			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
myocardial infarction				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
myocardial ischaemia				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
cerebral haemorrhage				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
headache				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
migraine				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
syncope				
alternative dictionary used: MedDRA 18.0				

subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
cataract			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
chronic gastritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
duodenal ulcer			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
enterocolitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
gastric ulcer haemorrhage			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
umbilical hernia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
rheumatoid arthritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
acute hepatitis b			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
bronchitis haemophilus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
campylobacter gastroenteritis			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
cellulitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
diverticulitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
escherichia sepsis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
herpes zoster			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
infectious colitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
lung infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

meningitis bacterial			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pneumocystis jirovecii pneumonia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pneumonia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pyelonephritis acute			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
sepsis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
urinary tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of

subjects exposed has been adjusted accordingly.

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

Non-serious adverse events	Baricitinib	Baricitinib + MTX	Methotrexate
Total subjects affected by non-serious adverse events			
subjects affected / exposed	81 / 159 (50.94%)	129 / 215 (60.00%)	115 / 210 (54.76%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 159 (1.26%)	13 / 215 (6.05%)	7 / 210 (3.33%)
occurrences (all)	2	13	7
Pregnancy, puerperium and perinatal conditions			
pregnancy			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[2]	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	3 / 159 (1.89%)	8 / 215 (3.72%)	5 / 210 (2.38%)
occurrences (all)	3	8	5
oedema peripheral			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	5 / 215 (2.33%)	4 / 210 (1.90%)
occurrences (all)	1	6	5
Respiratory, thoracic and mediastinal disorders			
catarrh			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used:			

MedDRA 18.0			
subjects affected / exposed	5 / 159 (3.14%)	6 / 215 (2.79%)	13 / 210 (6.19%)
occurrences (all)	7	6	14
sinus congestion			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	6 / 159 (3.77%)	2 / 215 (0.93%)	4 / 210 (1.90%)
occurrences (all)	6	2	4
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	13 / 215 (6.05%)	5 / 210 (2.38%)
occurrences (all)	1	15	5
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	7 / 215 (3.26%)	3 / 210 (1.43%)
occurrences (all)	0	8	3
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	4 / 159 (2.52%)	10 / 215 (4.65%)	2 / 210 (0.95%)
occurrences (all)	5	11	2
blood creatinine increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
liver function test abnormal			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
lymphocyte count increased			

alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	4 / 159 (2.52%)	1 / 215 (0.47%)	3 / 210 (1.43%)
occurrences (all)	4	1	3
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
arthropod bite			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
joint injury			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
thermal burn			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
wrist fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
cardiomegaly			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
left ventricular hypertrophy			
alternative dictionary used:			

MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	3 / 215 (1.40%)	5 / 210 (2.38%)
occurrences (all)	1	4	6
headache			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	5 / 159 (3.14%)	6 / 215 (2.79%)	3 / 210 (1.43%)
occurrences (all)	6	7	3
sciatica			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	4 / 159 (2.52%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	4	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 159 (1.26%)	6 / 215 (2.79%)	2 / 210 (0.95%)
occurrences (all)	2	6	2
thrombocytosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	4 / 159 (2.52%)	3 / 215 (1.40%)	0 / 210 (0.00%)
occurrences (all)	4	3	0
Ear and labyrinth disorders			
ear pruritus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
scleritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
scleromalacia			

alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	3 / 159 (1.89%)	1 / 215 (0.47%)	6 / 210 (2.86%)
occurrences (all)	4	1	6
constipation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 159 (1.26%)	7 / 215 (3.26%)	3 / 210 (1.43%)
occurrences (all)	3	8	3
diarrhoea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	3 / 159 (1.89%)	5 / 215 (2.33%)	12 / 210 (5.71%)
occurrences (all)	3	6	15
dyspepsia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	3 / 159 (1.89%)	8 / 215 (3.72%)	1 / 210 (0.48%)
occurrences (all)	3	9	1
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	5 / 215 (2.33%)	1 / 210 (0.48%)
occurrences (all)	0	5	1
large intestine polyp			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	7 / 159 (4.40%)	20 / 215 (9.30%)	13 / 210 (6.19%)
occurrences (all)	7	26	16
stomatitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	5 / 159 (3.14%)	5 / 215 (2.33%)	6 / 210 (2.86%)
occurrences (all)	5	8	6
Hepatobiliary disorders			
hepatic function abnormal			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	8 / 215 (3.72%)	5 / 210 (2.38%)
occurrences (all)	1	9	5
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	6 / 215 (2.79%)	5 / 210 (2.38%)
occurrences (all)	1	6	5
dermatitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
eczema asteatotic			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
miliaria			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
petechiae			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
purpura			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
polyuria			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
hypothyroidism			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	3 / 159 (1.89%)	9 / 215 (4.19%)	5 / 210 (2.38%)
occurrences (all)	3	10	5
muscle spasms			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	2 / 159 (1.26%)	7 / 215 (3.26%)	1 / 210 (0.48%)
occurrences (all)	2	7	2
rheumatoid arthritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	3 / 159 (1.89%)	1 / 215 (0.47%)	7 / 210 (3.33%)
occurrences (all)	3	1	7
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	5 / 159 (3.14%)	9 / 215 (4.19%)	4 / 210 (1.90%)
occurrences (all)	5	10	4
gastroenteritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	10 / 159 (6.29%)	6 / 215 (2.79%)	4 / 210 (1.90%)
occurrences (all)	10	6	4
hepatitis e			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	3 / 159 (1.89%)	5 / 215 (2.33%)	0 / 210 (0.00%)
occurrences (all)	3	5	0
influenza			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	7 / 159 (4.40%)	11 / 215 (5.12%)	4 / 210 (1.90%)
occurrences (all)	7	11	4
nasopharyngitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	16 / 159 (10.06%)	21 / 215 (9.77%)	17 / 210 (8.10%)
occurrences (all)	21	32	20
pharyngitis			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	2 / 159 (1.26%)	7 / 215 (3.26%)	4 / 210 (1.90%)
occurrences (all)	2	9	6
rhinitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	2 / 215 (0.93%)	7 / 210 (3.33%)
occurrences (all)	1	3	7
sinusitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 159 (0.63%)	7 / 215 (3.26%)	5 / 210 (2.38%)
occurrences (all)	1	8	5
upper respiratory tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	12 / 159 (7.55%)	16 / 215 (7.44%)	15 / 210 (7.14%)
occurrences (all)	14	19	15
urinary tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	6 / 159 (3.77%)	14 / 215 (6.51%)	7 / 210 (3.33%)
occurrences (all)	7	16	7
vaginal infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[3]	0 / 159 (0.00%)	0 / 215 (0.00%)	0 / 210 (0.00%)
occurrences (all)	0	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[4]	0 / 121 (0.00%)	6 / 156 (3.85%)	1 / 148 (0.68%)
occurrences (all)	0	8	1
Metabolism and nutrition disorders			
dyslipidaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 159 (1.26%)	8 / 215 (3.72%)	2 / 210 (0.95%)
occurrences (all)	2	8	2
hypercholesterolaemia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	4 / 159 (2.52%)	4 / 215 (1.86%)	3 / 210 (1.43%)
occurrences (all)	4	4	3
hyperlipidaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	3 / 159 (1.89%)	6 / 215 (2.79%)	1 / 210 (0.48%)
occurrences (all)	3	6	1

Non-serious adverse events	Rescue	Baricitinib - Follow-up	Methotrexate - Follow-up
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 39 (53.85%)	2 / 15 (13.33%)	2 / 25 (8.00%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Pregnancy, puerperium and perinatal conditions			
pregnancy			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[2]	1 / 28 (3.57%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
pyrexia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

catarrh			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
cough			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
sinus congestion			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
blood creatinine increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0

liver function test abnormal			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
lymphocyte count increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
weight increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
arthropod bite			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
joint injury			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
thermal burn			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 39 (5.13%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
wrist fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			

cardiomegaly			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
left ventricular hypertrophy			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
sciatica			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
thrombocytosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
ear pruritus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Eye disorders			

scleritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
scleromalacia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	1 / 15 (6.67%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
diarrhoea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
large intestine polyp			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
nausea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
stomatitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
vomiting			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
hepatic function abnormal			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
dermatitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
eczema asteatotic			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	1 / 15 (6.67%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
miliaria			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 39 (0.00%)	1 / 15 (6.67%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
petechiae			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
pruritus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
purpura			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	1 / 15 (6.67%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
polyuria			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
hypothyroidism			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	1 / 25 (4.00%)
occurrences (all)	0	0	1
back pain			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
muscle spasms			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
rheumatoid arthritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
hepatitis e			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
herpes zoster			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
influenza			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
pharyngitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
rhinitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
urinary tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
vaginal infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[3]	1 / 28 (3.57%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[4]	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
dyslipidaemia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 39 (0.00%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 39 (2.56%)	0 / 15 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Baricitinib + MTX - Follow-up		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 28 (0.00%)		
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Pregnancy, puerperium and perinatal conditions			
pregnancy			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[2]	0 / 28 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
oedema peripheral			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
pyrexia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
catarrh			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
cough			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
sinus congestion			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
blood creatinine increased			

alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
liver function test abnormal			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
lymphocyte count increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
weight increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
arthropod bite			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
joint injury			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
thermal burn			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
wrist fracture			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
cardiomegaly			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
left ventricular hypertrophy			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
dizziness			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
headache			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
sciatica			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
thrombocytosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			

ear pruritus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Eye disorders			
scleritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
scleromalacia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
abdominal pain upper			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
constipation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
diarrhoea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
dyspepsia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
gastrooesophageal reflux disease			

alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
large intestine polyp			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
nausea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
stomatitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
vomiting			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
hepatic function abnormal			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
dermatitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
eczema asteatotic			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
miliaria			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
petechiae			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
pruritus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
purpura			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
polyuria			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
hypothyroidism			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			

arthralgia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
back pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
muscle spasms			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
rheumatoid arthritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
gastroenteritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
hepatitis e			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
herpes zoster			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
influenza			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
nasopharyngitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
pharyngitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
rhinitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
sinusitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
upper respiratory tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
urinary tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
vaginal infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[3]	0 / 28 (0.00%)		
occurrences (all)	0		
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[4]	0 / 28 (0.00%)		
occurrences (all)	0		

Metabolism and nutrition disorders			
dyslipidaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
hypercholesterolaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
hyperlipidaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		

Notes:

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.
[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported