Clinical trial results:
A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study Evaluating the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Moderately to Severely Active Rheumatoid Arthritis Who Have Had an Inadequate Response to Tumor Necrosis Factor Inhibitors

Summary

EudraCT number	2012-002323-15
Trial protocol	IT PL BE GB AT DK ES NL GR HR
Global end of trial date	02 September 2014

Results information

Result version number	v2 (current)
This version publication date	07 March 2018
First version publication date	26 March 2017
Version creation reason	• New data added to full data set Revision required

Trial information

Trial identification

Sponsor protocol code	14058

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01721044
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 14058 , Trial Alias: I4V-MC-JADW

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	02 September 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	02 September 2014
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 4 milligram (mg) once daily is superior to placebo in the treatment of participants with moderately to severely active Rheumatoid Arthritis (RA) who have had an inadequate response to a tumor necrosis factor (TNF) inhibitor, despite ongoing treatment with conventional synthetic 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	16 January 2013
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: 21
Country: Number of subjects enrolled	Australia: 21
Country: Number of subjects enrolled	Austria: 16
Country: Number of subjects enrolled	Belgium: 3
Country: Number of subjects enrolled	Canada: 8
Country: Number of subjects enrolled	Denmark: 6
Country: Number of subjects enrolled	France: 24
Country: Number of subjects enrolled	Germany: 19
Country: Number of subjects enrolled	Greece: 9
Country: Number of subjects enrolled	Israel: 30
Country: Number of subjects enrolled	Italy: 8
Country: Number of subjects enrolled	Japan: 20
Country: Number of subjects enrolled	Mexico: 31
Country: Number of subjects enrolled	Netherlands: 2
Country: Number of subjects enrolled	Poland: 32
Country: Number of subjects enrolled	Korea, Republic of: 10
Country: Number of subjects enrolled	Spain: 27
Country: Number of subjects enrolled	Switzerland: 7
Country: Number of subjects enrolled	Turkey: 3

Country: Number of subjects enrolled	United Kingdom: 4
Country: Number of subjects enrolled	United States: 226
Worldwide total number of subjects	527
EEA total number of subjects	150

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)	411
From 65 to 84 years	116
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No Text Entered

Pre-assignment

Screening details:

Participants who did not adequately respond (nonresponders) to study drug were eligible for rescue treatment with baricitinib 4 mg beginning at Week 16. Nonresponders were defined as lack of improvement of at least 20% in both tender joint count and swollen joint count at both Weeks 14 and 16 compared to baseline.

Period 1

Period 1 title	Overall Study
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	Placebo

Arm description:

Placebo administered orally (PO) once daily (QD) through Week 24. Participants continued to take background conventional synthetic drug (DMARD) therapy throughout study.

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

Dosage and administration details:

Placebo administered orally once daily through Week 24. Starting at Week 16, participants who are nonresponders will be rescued with baricitinib 4 milligram (mg) orally once daily through Week 24.

Arm title	Baricitinib 2 mg

Arm description:

Baricitinib 2 milligram (mg) administered PO QD through Week 24. Participants continued to take background DMARD therapy throughout study.

Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	
Other name	LY3009104, INCB 028050
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Baricitinib 2 mg administered orally once daily through Week 24. Starting at Week 16, participants who are nonresponders will be rescued with baricitinib 4 mg orally once daily through Week 24.

Arm title	Baricitinib 4 mg

Arm description:

Baricitinib 4 mg administered PO QD through Week 24. Participants continued to take background DMARD therapy throughout study.

Arm type	Experimental

Investigational medicinal product name	Baricitinib
Investigational medicinal product code	
Other name	LY3009104, INCB 028050
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Baricitinib 4 mg administered orally once daily through Week 24. Starting at Week 16, participants who are nonresponders will be rescued with baricitinib 4 mg orally once daily through Week 24.

Number of subjects in period 1	Placebo	Baricitinib 2 mg	Baricitinib 4 mg
Started	176	174	177
Rescue week 16-24	56 [1]	38 [2]	33 [3]
Completed	144	157	158
Not completed	32	17	19
Adverse event, serious fatal	-	-	1
Physician decision	1	-	2
Consent withdrawn by subject	7	6	1
Adverse event, non-fatal	7	7	10
Lost to follow-up	-	-	1
Lack of efficacy	16	4	4
Protocol deviation	1	-	-

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: Nonresponders were eligible for rescue treatment with baricitinib 4 mg beginning at Week 16. Nonresponders were defined as lack of improvement of at least 20% in both tender joint count and swollen joint count at both Weeks 14 and 16 compared to baseline.

[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: Nonresponders were eligible for rescue treatment with baricitinib 4 mg beginning at Week 16. Nonresponders were defined as lack of improvement of at least 20% in both tender joint count and swollen joint count at both Weeks 14 and 16 compared to baseline.

[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: Nonresponders were eligible for rescue treatment with baricitinib 4 mg beginning at Week 16. Nonresponders were defined as lack of improvement of at least 20% in both tender joint count and swollen joint count at both Weeks 14 and 16 compared to baseline.

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	Placebo

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 2 mg

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 4 mg

Arm description:

Includes participants who were rescued to baricitinib 4 mg. 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

Number of subjects in period 2[4]	Placebo	Baricitinib 2 mg	Baricitinib 4 mg
Started	19	9	20
Completed	19	9	20

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	Placebo
Reporting group description:	
Placebo administered orally (PO) once daily (QD) through Week 24. Participants continued to take background conventional synthetic drug (DMARD) therapy throughout study.	
Reporting group title	Baricitinib 2 mg
Reporting group description:	
Baricitinib 2 milligram (mg) administered PO QD through Week 24. Participants continued to take background DMARD therapy throughout study.	
Reporting group title	Baricitinib 4 mg
Reporting group description:	
Baricitinib 4 mg administered PO QD through Week 24. Participants continued to take background DMARD therapy throughout study.	

Reporting group values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg
Number of subjects	176	174	177
Age categorical Units: Subjects			
Age Continuous Units: Years			
arithmetic mean	56	55.1	55.9
standard deviation	± 10.7	± 11.1	± 11.3
Gender, Male/Female Units: Participants			
Female	145	137	149
Male	31	37	28
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	9	12	11
Asian	11	9	12
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	8	9	7
White	147	144	144
More than one race	1	0	0
Unknown or Not Reported	0	0	3
Region of Enrollment Units: Subjects			
Argentina	9	5	7
Australia	8	9	4
Austria	5	3	8
Belgium	1	1	1
Canada	1	4	3
Denmark	2	3	1
France	7	10	7
Germany	8	5	6
Greece	4	3	2

Israel	9	8	13
Italy	2	3	3
Japan	6	6	8
Mexico	9	12	10
Netherlands	0	1	1
Poland	10	13	9
Korea, Republic of	4	3	3
Spain	10	7	10
Switzerland	1	2	4
Turkey	1	1	1
United Kingdom	2	1	1
United States	77	74	75
Duration of Rheumatoid Arthritis			
Time from Symptom Onset of Rheumatoid Arthritis			
Units: Years			
arithmetic mean	14	13.7	14.3
standard deviation	± 9.6	± 8	± 9.4
Tender Joint Count of 68 Evaluable Joints			
N-obs: 174, 174, 177 and 525, respectively. Tender joint count based on 68 joints.			
Units: Number of Joints			
arithmetic mean	28.3	31	28.1
standard deviation	± 16.4	± 16.3	± 15.6
Swollen Joint Count of 66 Evaluable Joints			
N-obs: 174,174,177 and 525, respectively. Swollen joint count based on 66 joints.			
Units: Number of Joints			
arithmetic mean	17.2	18.6	16.3
standard deviation	± 10.8	± 12.3	± 8.9
High Sensitivity C-Reactive Protein (hsCRP)			
Units: milligrams/liter (mg/L)			
arithmetic mean	20.64	19.87	19.76
standard deviation	± 25.26	± 22.48	± 24.84

Reporting group values	Total		
Number of subjects	527		
Age categorical			
Units: Subjects			

Age Continuous			
Units: Years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female			
Units: Participants			
Female	431		
Male	96		
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	32		
Asian	32		

Native Hawaiian or Other Pacific Islander	0		
Black or African American	24		
White	435		
More than one race	1		
Unknown or Not Reported	3		
Region of Enrollment Units: Subjects			
Argentina	21		
Australia	21		
Austria	16		
Belgium	3		
Canada	8		
Denmark	6		
France	24		
Germany	19		
Greece	9		
Israel	30		
Italy	8		
Japan	20		
Mexico	31		
Netherlands	2		
Poland	32		
Korea, Republic of	10		
Spain	27		
Switzerland	7		
Turkey	3		
United Kingdom	4		
United States	226		
Duration of Rheumatoid Arthritis			
Time from Symptom Onset of Rheumatoid Arthritis			
Units: Years arithmetic mean standard deviation	- -		
Tender Joint Count of 68 Evaluable Joints			
N-obs: 174, 174, 177 and 525, respectively. Tender joint count based on 68 joints.			
Units: Number of Joints arithmetic mean standard deviation	- -		
Swollen Joint Count of 66 Evaluable Joints			
N-obs: 174,174,177 and 525, respectively. Swollen joint count based on 66 joints.			
Units: Number of Joints arithmetic mean standard deviation	- -		
High Sensitivity C-Reactive Protein (hsCRP) Units: milligrams/liter (mg/L) arithmetic mean standard deviation	- -		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Placebo administered orally (PO) once daily (QD) through Week 24. Participants continued to take background conventional synthetic drug (DMARD) therapy throughout study.	
Reporting group title	Baricitinib 2 mg
Reporting group description:	
Baricitinib 2 milligram (mg) administered PO QD through Week 24. Participants continued to take background DMARD therapy throughout study.	
Reporting group title	Baricitinib 4 mg
Reporting group description:	
Baricitinib 4 mg administered PO QD through Week 24. Participants continued to take background DMARD therapy throughout study.	
Reporting group title	Placebo
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 2 mg
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 4 mg
Reporting group description:	
Includes participants who were rescued to baricitinib 4 mg. No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug.	
Subject analysis set title	PK population 2mg Baricitinib
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
All randomized participants who received at least 1 dose of 2 mg baricitinib with evaluable PK data.	
Subject analysis set title	PK population 4mg Baricitinib
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
All randomized participants who received at least 1 dose of 4 mg baricitinib with evaluable PK data.	

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

End point title	Percentage of Participants Achieving American College of Rheumatology 20% (ACR20) Response
End point description:	
ACR20 Responder Index is a composite of clinical, laboratory, and functional measures in rheumatoid arthritis. 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 timepoint are deemed non-responders. Analysis Population Description: Modified Intent-to-Treat (mITT) population includes all randomized participants who received at least 1 dose of the study drug. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using non-responder imputation (NRI).	
End point type	Primary
End point timeframe:	
Week 12	

End point values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	174	177	
Units: Percentage of Participants				
number (not applicable)	27.3	48.9	55.4	

Statistical analyses

Statistical analysis title	Primary Outcome Statisical Analysis
Comparison groups	Placebo v Baricitinib 4 mg
Number of subjects included in analysis	353
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Regression, Logistic
Confidence interval	
sides	2-sided

Secondary: Change from Baseline in HAQ-DI Score

End point title	Change from Baseline in HAQ-DI Score

End point description:

The HAQ-DI questionnaire 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 were averaged to calculate the HAQ-DI score, which ranged from 0 (no disability) to 3 (worst disability). A decrease in HAQ-DI score indicated an improvement in the participant's condition.

Analysis Population Description: mITT population includes all randomized participants who received at least 1 dose of the 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 12

End point values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	174	177	
Units: Units on a Scale				
arithmetic mean (standard deviation)	-0.2 (± 0.5)	-0.38 (± 0.51)	-0.42 (± 0.49)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Disease Activity Score Based on a 28-Joint Count (DAS28) High Sensitivity C-Reactive Protein (hsCRP)

End point title	Change from Baseline in the Disease Activity Score Based on a 28-Joint Count (DAS28) High Sensitivity C-Reactive Protein (hsCRP)

End point description:

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

Analysis Population Description: mITT population includes all randomized participants who received at least 1 dose of the 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 12

End point values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	174	174	177	
Units: Units on a Scale				
arithmetic mean (standard deviation)	-0.85 (± 1.19)	-1.53 (± 1.34)	-1.81 (± 1.43)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Simplified Disease Activity Index (SDAI) Score ≤3.3

End point title	Percentage of Participants Achieving 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 includes all randomized participants who received at least 1 dose of the 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

End point values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	174	177	
Units: Percent of Participants				
number (not applicable)	1.7	2.3	5.1	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving ACR20 Response

End point title	Percentage of Participants Achieving ACR20 Response

End point description:

ACR20 Responder Index is a composite of clinical, laboratory, and functional measures in rheumatoid arthritis. 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 using VAS, Patient's Global Assessment of Disease Activity using VAS, HAQ-DI, pain due to arthritis, 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 includes all randomized participants who received at least 1 dose of the 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	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	174	177	
Units: Percentage of Participants				
number (not applicable)	27.3	44.8	46.3	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving American Col0lege of Rheumatology 50% (ACR50) Response

End point title	Percentage of Participants Achieving American Col0lege of Rheumatology 50% (ACR50) Response

End point description:

ACR50 Responder Index is a 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, HAQ-DI, pain due to arthritis, 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 includes all randomized participants who received at least 1 dose of the 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 and Week 24

End point values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	174	177	
Units: Percentage of Participants				
number (not applicable)				
Week 12	8	20.1	28.2	
Week 24	13.1	23	29.4	

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 a composite of clinical, laboratory, and functional measures in RA. ACR70 Responder is a participant who has at least 70% 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, HAQ-DI, pain due to arthritis, 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 includes all randomized participants who received at least 1 dose of the 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 and Week 24

End point values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	174	177	
Units: Percentage of Participants				
number (not applicable)				
Week 12	2.3	12.6	11.3	
Week 24	3.4	13.2	16.9	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in DAS28 - Erythrocyte Sedimentation Rate (ESR)

End point title	Change from Baseline in DAS28 - Erythrocyte Sedimentation Rate (ESR)

End point description:

DAS28 consisted of composite score of following variables: tender joint count (TJC28), swollen joint count (SJC28), ESR (millimeters per hour), and Patient's Global Assessment of Disease Activity. DAS28 was calculated using 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. Total scores ranged from 1.0-9.4, where lower scores indicated less disease activity.

Analysis Population Description: mITT population includes all randomized participants who received at least 1 dose of the study drug. 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 12

End point values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	168	169	173	
Units: Units on a Scale				
arithmetic mean (standard deviation)	-0.92 (± 1.21)	-1.52 (± 1.37)	-1.8 (± 1.44)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Clinical Disease Activity Index Score

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

End point description:

The Clinical Disease Activity Index (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 includes all randomized participants who received at least 1 dose of the study drug. 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

End point values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	170	169	171	
Units: Units on a Scale				
arithmetic mean (standard deviation)	-12.19 (± 16.96)	-17.17 (± 16.96)	-20.3 (± 16.29)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Measures of SDAI Score

End point title	Change from Baseline in Measures of SDAI Score

End point description:

The 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), 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 SDAI is calculated by summing the values of the 5 components. Lower scores indicated less disease activity.

Analysis Population Description: mITT population includes all randomized participants who received at least 1 dose of the study drug. 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

End point values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	170	169	171	
Units: Units on a Scale				
arithmetic mean (standard deviation)	-12.07 (± 17.5)	-17.8 (± 17.5)	-21.26 (± 17.01)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving ACR/EULAR Remission – Boolean Remission

End point title	Percentage of Participants Achieving ACR/EULAR Remission – Boolean Remission

End point description:

The ACR/EULAR definitions of RA remission includes 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 includes all randomized participants who received at least 1 dose of the 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	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	174	177	
Units: Percentage of Participants				
number (not applicable)	1.1	4	6.8	

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 that day. 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 includes all randomized participants who received at least 1 dose of the study drug. 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

End point values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	172	175	
Units: Minutes				
median (confidence interval 95%)	-8 (-15 to 0)	-25.5 (-40 to -15)	-27 (-40 to -15)	

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:

A participant-administered, single-item, 11-point horizontal scale anchored at 0 and 10, with 0 representing (no tiredness) and 10 representing (as bad as you can imagine). Participants rate their tiredness by selecting the one number that describes their worst level of tiredness during the past 24 hours. Total scores ranged from 0-10.

Analysis Population Description: mITT population includes all randomized participants who received at least 1 dose of the study drug. 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

End point values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	172	175	
Units: Units on a Scale				
arithmetic mean (standard deviation)	-1.1 (± 2.3)	-1.8 (± 2.7)	-2 (± 2.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Worst Joint Pain NRS

End point title	Change from Baseline in Worst Joint Pain NRS

End point description:

Participant-administered, single-item, 11-point horizontal scale anchored at 0 and 10, with 0 representing (no joint pain) and 10 representing (pain as bad as you can imagine). Participants rate their joint pain by selecting the one number that describes their worst level of joint pain during the past 24 hours. Total scores ranged from 0-10.

Analysis Population Description: mITT population includes all randomized participants who received at least 1 dose of the study drug. 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

End point values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	172	172	175	
Units: Units on a Scale				
arithmetic mean (standard deviation)	-1.2 (± 2.4)	-2.1 (± 2.5)	-2.5 (± 2.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Functional Assessment of Chronic Illness Therapy-Fatigue Scale Scores

End point title	Change from Baseline in Functional Assessment of Chronic Illness Therapy-Fatigue Scale Scores

End point description:

The Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) Scale is a brief 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 includes all randomized participants who received at least 1 dose of the study drug. 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 12, Week 24

End point values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	170	170	174	
Units: Units on a Scale				
arithmetic mean (standard deviation)				
Week 12	5.9 (± 10.5)	8.8 (± 10)	8.5 (± 9.9)	
Week 24	6.6 (± 10.7)	8.8 (± 10.4)	9.7 (± 10.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Mental Component Score (MCS), 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), 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 (mental [MCS] and physical [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.

Analysis Population Description: mITT population includes all randomized participants who received at least 1 dose of the study drug. 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 12, Week 24

End point values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	168	168	174	
Units: Units on a Scale				
arithmetic mean (standard deviation)				
Week 12 MCS	1.6 (± 10.7)	3.4 (± 9.7)	2.4 (± 10)	
Week 24 MCS	2.5 (± 10.8)	3.2 (± 11.5)	3.3 (± 10.6)	
Week 12 PCS	3.3 (± 8)	6.3 (± 8.8)	6.4 (± 8.8)	
Week 24 PCS	2.4 (± 8.2)	6.4 (± 8.9)	7 (± 9.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in European Quality of Life-5 Dimensions-5 Level Scores

End point title	Change from Baseline in European Quality of Life-5 Dimensions-5 Level Scores

End point description:

EQ-5D-5L is a standardized measure of health status. The first component is a descriptive system of the respondent's health comprised of the 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. The second component is a self-perceived health score which is assessed using a VAS that ranged from 0 to 100 millimeter (mm), where 0 mm indicated the worst health you can imagine and 100 mm indicated the best health you can imagine.

Population Description: mITT population. Missing data were imputed using mLOCF.

End point type	Secondary

End point timeframe:

Baseline, Week 12, Week 24

End point values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	168	168	173	
Units: Units on a Scale				
arithmetic mean (standard deviation)				
Index Score (US Algorithm) Wk 12 (N=168,168,173)	0.035 (± 0.167)	0.08 (± 0.152)	0.128 (± 0.148)	
Index Score (US Algorithm) Wk 24 (N=167,168,173)	0.042 (± 0.166)	0.082 (± 0.17)	0.128 (± 0.157)	
Index Score (UK Algorithm) Wk 12 (N=168,168,173)	0.052 (± 0.25)	0.116 (± 0.224)	0.191 (± 0.224)	
Index Score (UK Algorithm) Wk 24 (N=167,168,173)	0.064 (± 0.245)	0.122 (± 0.25)	0.192 (± 0.237)	
Self-Perceived Health Wk 12 (N=168,168,173)	4.1 (± 29)	14.1 (± 24.2)	10.3 (± 27.3)	
Self-Perceived Health Wk 24 (N=167,168,173)	3.8 (± 27.8)	11.4 (± 26.5)	13.3 (± 29)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

The WPAI-RA participant 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. Using 6

questions, it yields four types of scores: absenteeism (work time missed), presenteeism (impairment at work), work productivity loss (overall work impairment), and activity impairment, with outcomes expressed as impairment percentages. Percentage work time missed absenteeism: Q2/(Q2+Q4)*100, Percentage impairment while working presenteeism: Q5/10*100; Percentage overall work impairment work productivity loss: Q2/(Q2+Q4)+[(1-Q2/(Q2+Q4))x(Q5/10)]*100; Percentage activity impairment activity impairment: Q6/10*100. Higher numbers indicate greater impairment and less productivity, that is, worse outcomes.

Population: mITT population includes all randomized participants who received at least 1 dose of the study drug.

End point type	Secondary

End point timeframe:

Baseline, Week 12, Week 24

End point values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	176	174	177	
Units: Percentage of Impairment				
arithmetic mean (standard deviation)				
Absenteeism Week 12 (n=39, 57, 46)	3.2 (± 23.8)	-6.7 (± 26.6)	-6.5 (± 22.1)	
Absenteeism Week 24 (n=22, 37, 38)	0.9 (± 12.4)	-1.9 (± 31.4)	-2.3 (± 29.5)	
Presenteeism Week 12 (n=37, 54, 43)	-4.1 (± 26.4)	12 (± 24)	-10.5 (± 24)	
Presenteeism Week 24 (n=21, 35, 34)	-7.1 (± 30.5)	-11.4 (± 24.9)	-15.6 (± 25.4)	
Work Productivity Loss Week 12 (n=37, 54, 43)	-4.2 (± 27.8)	-13.7 (± 26.7)	-12.3 (± 24.8)	
Work Productivity Loss Week 24 (n=21, 35, 34)	-6 (± 33.4)	-13.2 (± 27.6)	-14.8 (± 32.4)	
Activity Impairment Week 12 (n=157, 162, 165)	-10.4 (± 22.8)	-16 (± 25.5)	-18.1 (± 24.8)	
Activity Impairment Week 24 (n= 91, 119, 125)	-15.7 (± 25.5)	-20.8 (± 23.7)	-25.8 (± 25.2)	

Statistical analyses

No statistical analyses for this end point

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

End point title	Population Pharmacokinetics (PK): Maximum Concentration at Steady State of Dosing (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 (Baseline): 15 min. post-dose, 1 hour post-dose. Week 4 (Day 28 ±2 days): 2 to 4 hours post-dose. Week 8 (Day 56 ±3 days): 4 to 6 hours post-dose. Week 12 (Day 84 ±3 days): Pre-dose. Week 24 (Day 168 ±5 days): Pre-dose.

End point values	PK population 2mg Baricitinib	PK population 4mg Baricitinib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	185	210		
Units: nanomoles/Liter (nmol/L)				
geometric mean (geometric coefficient of variation)	65.6 (± 21.4)	130 (± 19.3)		

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 (Baseline): 15 min. post-dose, 1 hour post-dose. Week 4 (Day 28 ±2 days): 2 to 4 hours post-dose. Week 8 (Day 56 ±3 days): 4 to 6 hours post-dose. Week 12 (Day 84 ±3 days): Pre-dose. Week 24 (Day 168 ±5 days): Pre-dose.

End point values	PK population 2mg Baricitinib	PK population 4mg Baricitinib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	185	210		
Units: nanomoles*hour/Liter (nmol*h/L)				
geometric mean (geometric coefficient of variation)	615 (± 43.1)	1140 (± 38.7)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Entire Study	
Adverse event reporting additional description:	
I4V-MC-JADW	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	17.0

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Placebo administered orally (PO) once daily (QD) through Week 24. Participants continued to take background conventional synthetic drug (DMARD) therapy throughout study.	
Reporting group title	Baricitinib 2 mg
Reporting group description:	
Baricitinib 2 milligram (mg) administered PO QD through Week 24. Participants continued to take background DMARD therapy throughout study.	
Reporting group title	Baricitinib 4 mg
Reporting group description:	
Baricitinib 4 mg administered PO QD through Week 24. Participants continued to take background DMARD therapy throughout study.	
Reporting group title	Rescue (Weeks 16-24)
Reporting group description:	
Baricitinib 4 mg administered PO QD Weeks 16-24 only. Participants continued to take background DMARD therapy throughout study.	
Reporting group title	Placebo - 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 2 mg - 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 4 mg - Follow Up
Reporting group description:	
Includes participants who were rescued to baricitinib 4 mg. No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug.	

Serious adverse events	Placebo	Baricitinib 2 mg	Baricitinib 4 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 176 (7.95%)	8 / 174 (4.60%)	19 / 177 (10.73%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			

hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 176 (1.14%)	0 / 174 (0.00%)	0 / 177 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypertensive crisis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	1 / 174 (0.57%)	0 / 177 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral embolism			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	1 / 174 (0.57%)	0 / 177 (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			
medical device complication			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	1 / 174 (0.57%)	0 / 177 (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
pleuritic pain			

alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia aspiration			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	1 / 174 (0.57%)	0 / 177 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary mass			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
Psychiatric disorders			
confusional state			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
delirium			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
Investigations			
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
hepatic enzyme increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
weight decreased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
accident at work			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acetabulum fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
alcohol poisoning			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
bone contusion			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac contusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
concussion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	1 / 174 (0.57%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
facial bones fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
fall			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fractured sacrum			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
hand fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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

laceration			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
ligament sprain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	1 / 174 (0.57%)	0 / 177 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower limb fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
muscle rupture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	0 / 177 (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
road traffic accident			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	1 / 174 (0.57%)	0 / 177 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
ulna fracture			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
coronary artery disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	2 / 177 (1.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tachycardia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
Nervous system disorders			
basilar artery thrombosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
carpal tunnel syndrome			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	1 / 174 (0.57%)	0 / 177 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient global amnesia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertebral artery thrombosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
haemorrhagic anaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
iron deficiency anaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
leukocytosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
thrombocytopenia			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
motion sickness			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vertigo positional			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
diverticulum intestinal haemorrhagic			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	0 / 177 (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
inguinal hernia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
oral disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	1 / 174 (0.57%)	0 / 177 (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
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 176 (0.00%)	1 / 174 (0.57%)	0 / 177 (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
Renal and urinary disorders			
renal failure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
Musculoskeletal and connective tissue disorders			
osteoarthritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	1 / 174 (0.57%)	0 / 177 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rheumatoid arthritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	3 / 176 (1.70%)	0 / 174 (0.00%)	2 / 177 (1.13%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
campylobacter gastroenteritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	1 / 174 (0.57%)	0 / 177 (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 17.0			

subjects affected / exposed	2 / 176 (1.14%)	0 / 174 (0.00%)	0 / 177 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis viral			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral discitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	1 / 174 (0.57%)	0 / 177 (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
osteomyelitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	1 / 174 (0.57%)	0 / 177 (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 17.0			
subjects affected / exposed	1 / 176 (0.57%)	1 / 174 (0.57%)	0 / 177 (0.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

tooth infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
upper respiratory tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	1 / 174 (0.57%)	1 / 177 (0.56%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	2 / 177 (1.13%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vulval abscess			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[1]	0 / 145 (0.00%)	0 / 137 (0.00%)	1 / 149 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
electrolyte imbalance			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
hyperglycaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (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
malnutrition			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	0 / 177 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Rescue (Weeks 16-24)	Placebo - Follow Up	Baricitinib 2 mg - Follow Up
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 127 (1.57%)	0 / 19 (0.00%)	1 / 9 (11.11%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
hypertensive crisis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
peripheral embolism			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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			
medical device complication			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
pleuritic pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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 aspiration			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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 mass			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
Psychiatric disorders			
confusional state			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
delirium			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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			
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
hepatic enzyme increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
weight decreased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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			
accident at work			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
acetabulum fracture			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
alcohol poisoning			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
bone contusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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 contusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
concussion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
facial bones fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
fall			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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

fractured sacrum			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
hand fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
laceration			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
ligament sprain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
lower limb fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
muscle rupture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 127 (0.79%)	0 / 19 (0.00%)	0 / 9 (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
road traffic accident			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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 fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
ulna fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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			
coronary artery disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
tachycardia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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			
basilar artery thrombosis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
carpal tunnel syndrome			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 127 (0.79%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
transient global amnesia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
vertebral artery thrombosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
Blood and lymphatic system disorders			
haemorrhagic anaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
iron deficiency anaemia			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
leukocytosis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
thrombocytopenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
Ear and labyrinth disorders			
motion sickness			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
vertigo positional			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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			
diverticulum intestinal haemorrhagic			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
inguinal hernia			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
oral disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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			
renal failure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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			
osteoarthritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
rheumatoid arthritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 127 (0.79%)	0 / 19 (0.00%)	0 / 9 (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
synovitis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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			
campylobacter gastroenteritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
gastroenteritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
gastroenteritis viral			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
intervertebral discitis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
osteomyelitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
tooth infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
upper respiratory tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
vulval abscess			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[1]	0 / 113 (0.00%)	0 / 16 (0.00%)	0 / 9 (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

Metabolism and nutrition disorders			
electrolyte imbalance			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
hyperglycaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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
malnutrition			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (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 4 mg - Follow Up		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
hypertensive crisis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
peripheral arterial occlusive disease			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
peripheral embolism				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
medical device complication				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (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 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pleuritic pain				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonia aspiration				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pulmonary mass				
alternative dictionary used: MedDRA 17.0				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
confusional state				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
delirium				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
blood alkaline phosphatase increased				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
blood creatine phosphokinase increased				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hepatic enzyme increased				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
weight decreased				
alternative dictionary used: MedDRA 17.0				

subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
accident at work			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
acetabulum fracture			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
alcohol poisoning			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
bone contusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
cardiac contusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
concussion			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
facial bones fracture				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
fall				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
fractured sacrum				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hand fracture				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
laceration				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ligament sprain				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

lower limb fracture				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
muscle rupture				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
road traffic accident				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
spinal fracture				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ulna fracture				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
coronary artery disease				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
myocardial infarction				
alternative dictionary used: MedDRA 17.0				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tachycardia				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
basilar artery thrombosis				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
carpal tunnel syndrome				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
headache				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
transient global amnesia				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
vertebral artery thrombosis				
alternative dictionary used: MedDRA 17.0				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
haemorrhagic anaemia				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
iron deficiency anaemia				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
leukocytosis				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
thrombocytopenia				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ear and labyrinth disorders				
motion sickness				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
vertigo positional				
alternative dictionary used: MedDRA 17.0				

subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
diverticulum intestinal haemorrhagic			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
inguinal hernia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
oral disorder			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (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 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
renal failure			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
osteoarthritis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
rheumatoid arthritis				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
synovitis				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
campylobacter gastroenteritis				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cellulitis				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastroenteritis				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastroenteritis viral				
alternative dictionary used: MedDRA 17.0				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
herpes zoster				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
intervertebral discitis				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
osteomyelitis				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonia				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tooth infection				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
upper respiratory tract infection				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (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 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
vulval abscess			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[1]	0 / 18 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
electrolyte imbalance			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
hyperglycaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
malnutrition			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (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	Placebo	Baricitinib 2 mg	Baricitinib 4 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	79 / 176 (44.89%)	105 / 174 (60.34%)	102 / 177 (57.63%)

Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	4 / 176 (2.27%)	7 / 174 (4.02%)	9 / 177 (5.08%)
occurrences (all)	4	7	9
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	5 / 176 (2.84%)	6 / 174 (3.45%)	3 / 177 (1.69%)
occurrences (all)	5	6	4
pyrexia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	7 / 174 (4.02%)	3 / 177 (1.69%)
occurrences (all)	1	8	3
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	6 / 176 (3.41%)	2 / 174 (1.15%)	5 / 177 (2.82%)
occurrences (all)	6	2	5
oropharyngeal pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 176 (1.14%)	5 / 174 (2.87%)	5 / 177 (2.82%)
occurrences (all)	2	6	5
Psychiatric disorders			
insomnia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	0 / 177 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	0 / 174 (0.00%)	4 / 177 (2.26%)
occurrences (all)	1	0	6
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	5 / 177 (2.82%)
occurrences (all)	0	0	7
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	4 / 174 (2.30%)	6 / 177 (3.39%)
occurrences (all)	0	4	8
weight increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	4 / 174 (2.30%)	3 / 177 (1.69%)
occurrences (all)	1	4	3
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	4 / 176 (2.27%)	4 / 174 (2.30%)	1 / 177 (0.56%)
occurrences (all)	4	4	1
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	11 / 176 (6.25%)	17 / 174 (9.77%)	12 / 177 (6.78%)
occurrences (all)	12	17	12
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 176 (1.14%)	4 / 174 (2.30%)	1 / 177 (0.56%)
occurrences (all)	2	4	1
lymphopenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	0 / 177 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
episcleritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	0 / 177 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

abdominal pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	4 / 176 (2.27%)	5 / 174 (2.87%)	0 / 177 (0.00%)
occurrences (all)	4	5	0
abdominal pain upper			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	7 / 174 (4.02%)	4 / 177 (2.26%)
occurrences (all)	1	7	4
constipation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	4 / 176 (2.27%)	4 / 174 (2.30%)	3 / 177 (1.69%)
occurrences (all)	5	4	3
diarrhoea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	12 / 176 (6.82%)	10 / 174 (5.75%)	7 / 177 (3.95%)
occurrences (all)	12	10	7
gastritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	2 / 174 (1.15%)	4 / 177 (2.26%)
occurrences (all)	0	2	4
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	4 / 176 (2.27%)	3 / 174 (1.72%)	2 / 177 (1.13%)
occurrences (all)	4	3	2
nausea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	5 / 176 (2.84%)	7 / 174 (4.02%)	10 / 177 (5.65%)
occurrences (all)	6	9	10
vomiting			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 176 (1.14%)	4 / 174 (2.30%)	4 / 177 (2.26%)
occurrences (all)	2	5	4
Skin and subcutaneous tissue disorders			

rash			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 176 (1.14%)	5 / 174 (2.87%)	2 / 177 (1.13%)
occurrences (all)	2	5	2
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	8 / 176 (4.55%)	3 / 174 (1.72%)	5 / 177 (2.82%)
occurrences (all)	10	4	6
back pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	6 / 176 (3.41%)	8 / 174 (4.60%)	6 / 177 (3.39%)
occurrences (all)	6	8	6
muscle spasms			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 176 (1.14%)	3 / 174 (1.72%)	4 / 177 (2.26%)
occurrences (all)	2	3	4
myalgia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	5 / 174 (2.87%)	4 / 177 (2.26%)
occurrences (all)	1	6	4
neck pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	4 / 176 (2.27%)	2 / 174 (1.15%)	1 / 177 (0.56%)
occurrences (all)	4	2	1
pain in extremity			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	4 / 174 (2.30%)	1 / 177 (0.56%)
occurrences (all)	0	6	2
rheumatoid arthritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	7 / 176 (3.98%)	5 / 174 (2.87%)	8 / 177 (4.52%)
occurrences (all)	8	6	10
Infections and infestations			

bronchitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	6 / 176 (3.41%)	6 / 174 (3.45%)	10 / 177 (5.65%)
occurrences (all)	7	7	12
cervicitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[2]	0 / 145 (0.00%)	0 / 137 (0.00%)	0 / 149 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	0 / 174 (0.00%)	0 / 177 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	3 / 176 (1.70%)	4 / 174 (2.30%)	6 / 177 (3.39%)
occurrences (all)	3	4	7
herpes zoster			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	2 / 174 (1.15%)	6 / 177 (3.39%)
occurrences (all)	1	2	6
influenza			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 176 (1.14%)	4 / 174 (2.30%)	8 / 177 (4.52%)
occurrences (all)	2	4	10
nasopharyngitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	7 / 176 (3.98%)	12 / 174 (6.90%)	9 / 177 (5.08%)
occurrences (all)	7	13	10
pharyngitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 176 (0.00%)	4 / 174 (2.30%)	5 / 177 (2.82%)
occurrences (all)	0	4	5
rhinitis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	1 / 176 (0.57%)	5 / 174 (2.87%)	0 / 177 (0.00%)
occurrences (all)	1	5	0
sinusitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	8 / 174 (4.60%)	4 / 177 (2.26%)
occurrences (all)	1	8	4
upper respiratory tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	8 / 176 (4.55%)	15 / 174 (8.62%)	9 / 177 (5.08%)
occurrences (all)	8	17	11
urinary tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	6 / 176 (3.41%)	7 / 174 (4.02%)	8 / 177 (4.52%)
occurrences (all)	6	10	10
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[3]	0 / 145 (0.00%)	3 / 137 (2.19%)	0 / 149 (0.00%)
occurrences (all)	0	3	0
Metabolism and nutrition disorders			
hypercholesterolaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	2 / 176 (1.14%)	1 / 174 (0.57%)	7 / 177 (3.95%)
occurrences (all)	2	1	7
hyperlipidaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	1 / 176 (0.57%)	3 / 174 (1.72%)	5 / 177 (2.82%)
occurrences (all)	1	3	5

Non-serious adverse events	Rescue (Weeks 16-24)	Placebo - Follow Up	Baricitinib 2 mg - Follow Up
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 127 (4.72%)	2 / 19 (10.53%)	3 / 9 (33.33%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Psychiatric disorders			
insomnia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
weight increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	3 / 127 (2.36%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
lymphopenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Eye disorders			
episcleritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	1 / 19 (5.26%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
rash			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
back pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
neck pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
rheumatoid arthritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
cervicitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[2]	0 / 113 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	1 / 19 (5.26%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
gastroenteritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	4 / 127 (3.15%)	1 / 19 (5.26%)	0 / 9 (0.00%)
occurrences (all)	5	1	0
pharyngitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

sinusitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	1 / 19 (5.26%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
vulvovaginal candidiasis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed[3]	0 / 113 (0.00%)	0 / 16 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
hypercholesterolaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 127 (0.00%)	0 / 19 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Baricitinib 4 mg - Follow Up		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 20 (5.00%)		
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			

fatigue			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
pyrexia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
oropharyngeal pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
insomnia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
weight increased			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
lymphopenia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Eye disorders			
episcleritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
abdominal pain upper			

alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
constipation			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
diarrhoea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
gastritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
nausea			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
vomiting			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
rash			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			

arthralgia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
back pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
muscle spasms			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
myalgia			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
neck pain			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
pain in extremity			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
rheumatoid arthritis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 17.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
cervicitis			
alternative dictionary used: MedDRA 17.0			

subjects affected / exposed[2]	1 / 18 (5.56%)			
occurrences (all)	1			
conjunctivitis				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences (all)	0			
gastroenteritis				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences (all)	0			
herpes zoster				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences (all)	0			
influenza				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences (all)	0			
nasopharyngitis				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences (all)	0			
pharyngitis				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences (all)	0			
rhinitis				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences (all)	0			
sinusitis				
alternative dictionary used: MedDRA 17.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences (all)	0			

upper respiratory tract infection alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) urinary tract infection alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) vulvovaginal candidiasis alternative dictionary used: MedDRA 17.0 subjects affected / exposed[3] occurrences (all)	 0 / 20 (0.00%) 0 0 / 20 (0.00%) 0 0 / 18 (0.00%) 0		
Metabolism and nutrition disorders hypercholesterolaemia alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all) hyperlipidaemia alternative dictionary used: MedDRA 17.0 subjects affected / exposed occurrences (all)	 0 / 20 (0.00%) 0 0 / 20 (0.00%) 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.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported