



Clinical trial results:

A Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of Baricitinib (LY3009104) in Patients with Inadequate Response to Conventional Disease-Modifying Antirheumatic Drugs with Moderately to Severely Active Rheumatoid Arthritis

Summary

EudraCT number	2012-002339-27
Trial protocol	HU BE DE IT PT GB CZ SK ES
Global end of trial date	19 December 2014

Results information

Result version number	v1 (current)
This version publication date	26 March 2017
First version publication date	26 March 2017

Trial information

Trial identification

Sponsor protocol code	14059
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01721057
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 14059, Trial Alias: I4V-MC-JADX

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	19 December 2014
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	19 December 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 (QD) is superior to placebo in the treatment of participants with moderately to severely active Rheumatoid Arthritis (RA) who have had inadequate response to or are intolerant to at least 1 conventional disease-modifying antirheumatic drug (cDMARD)(cDMARD-IR [inadequate response] participants) and who have not received a biologic disease-modifying antirheumatic drug (DMARD).

Protection of trial subjects:

This study was conducted in accordance with 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:

Participants continued to take background conventional disease-modifying antirheumatic drug (cDMARD) therapy throughout study.

Evidence for comparator: -

Actual start date of recruitment	01 December 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 64
Country: Number of subjects enrolled	Australia: 15
Country: Number of subjects enrolled	Belgium: 11
Country: Number of subjects enrolled	Canada: 28
Country: Number of subjects enrolled	Croatia: 4
Country: Number of subjects enrolled	Czech Republic: 15
Country: Number of subjects enrolled	Germany: 9
Country: Number of subjects enrolled	Hungary: 20
Country: Number of subjects enrolled	India: 58
Country: Number of subjects enrolled	Italy: 10
Country: Number of subjects enrolled	Japan: 21
Country: Number of subjects enrolled	Korea, Republic of: 17
Country: Number of subjects enrolled	Mexico: 22
Country: Number of subjects enrolled	Poland: 51
Country: Number of subjects enrolled	Portugal: 5
Country: Number of subjects enrolled	Romania: 6

Country: Number of subjects enrolled	Russian Federation: 20
Country: Number of subjects enrolled	Slovakia: 11
Country: Number of subjects enrolled	Spain: 34
Country: Number of subjects enrolled	Taiwan: 82
Country: Number of subjects enrolled	United Kingdom: 5
Country: Number of subjects enrolled	United States: 176
Worldwide total number of subjects	684
EEA total number of subjects	181

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)	587
From 65 to 84 years	97
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

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

Pre-assignment

Screening details:

Participants who did not respond (nonresponders) to study drug were eligible for rescue treatment beginning at Week 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	Treatment Period (Weeks 0 to 24)
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 disease-modifying antirheumatic drug (cDMARD) therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD.

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

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

Dosage and administration details:

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

Arm title	Baricitinib 2 mg
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Arm description:

Baricitinib 2 mg PO QD through Week 24. Participants continued to take background cDMARD therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD.

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

Dosage and administration details:

Baricitinib 4 mg PO QD through week 24.

Participants continued to take background cDMARD therapy throughout study.

Arm title	Baricitinib 4 mg
Arm description: Baricitinib 4 mg PO QD through Week 24. Participants continued to take background cDMARD therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD.	
Arm type	Experimental
Investigational medicinal product name	Baricitinib
Investigational medicinal product code	
Other name	LY3009104
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Baricitinib 4 mg PO QD through Week 24.

Participants continued to take background cDMARD therapy throughout study.

Number of subjects in period 1	Placebo	Baricitinib 2 mg	Baricitinib 4 mg
Started	228	229	227
Rescue Week 16-24	55 ^[1]	21 ^[2]	15 ^[3]
Completed	199	209	203
Not completed	29	20	24
Adverse event, serious fatal	2	-	-
Consent withdrawn by subject	11	5	8
Physician decision	-	1	3
Adverse event, non-fatal	8	10	12
Lost to follow-up	1	-	-
Lack of efficacy	7	4	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: Participants who were nonresponders based on tender/swollen joint count were entered into the rescue milestone calculation.

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

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

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

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

Period 2	
Period 2 title	Follow Up
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor
Arms	
Are arms mutually exclusive?	Yes
Arm title	Placebo-Follow Up
Arm description:	
No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Baricitinib 2 mg- Follow Up
Arm description:	
No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Baricitinib 4 mg- Follow Up
Arm description:	
No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug.	
Includes participants who were rescued to Baricitinib 4 mg.	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 2^[4]	Placebo-Follow Up	Baricitinib 2 mg- Follow Up	Baricitinib 4 mg- Follow Up
Started	17	19	22
Completed	17	19	22

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
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Reporting group description:

Placebo administered orally (PO) once daily (QD) through Week 24. Participants continued to take background conventional disease-modifying antirheumatic drug (cDMARD) therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD.

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

Reporting group title	Baricitinib 2 mg
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Reporting group description:

Baricitinib 2 mg PO QD through Week 24. Participants continued to take background cDMARD therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD.

Reporting group title	Baricitinib 4 mg
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Reporting group description:

Baricitinib 4 mg PO QD through Week 24. Participants continued to take background cDMARD therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD.

Reporting group values	Placebo	Baricitinib 2 mg	Baricitinib 4 mg
Number of subjects	228	229	227
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	197	196	194
From 65-84 years	31	33	33
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	51.4	52.2	51.8
standard deviation	± 12.5	± 12.3	± 12.1
Gender, Male/Female			
Units: participants			
Female	189	184	187
Male	39	45	40
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	12	15	17
Not Hispanic or Latino	45	43	43
Unknown or Not Reported	171	171	167
Race (NIH/OMB)			

Units: Subjects			
American Indian or Alaska Native	3	2	9
Asian	60	61	59
Native Hawaiian or Other Pacific Islander	1	0	0
Black or African American	10	9	9
White	153	156	148
More than one race	1	1	1
Unknown or Not Reported	0	0	1
Region of Enrollment			
Units: Subjects			
Argentina	25	21	18
Australia	8	1	6
Belgium	1	4	6
Canada	10	10	8
Croatia	0	2	2
Czech Republic	7	5	3
Germany	4	2	3
Hungary	7	8	5
India	19	19	20
Italy	3	3	4
Japan	8	6	7
Korea, Republic of	6	7	4
Mexico	3	8	11
Poland	18	13	20
Portugal	2	2	1
Romania	1	3	2
Russian Federation	4	10	6
Slovakia	3	5	3
Spain	14	10	10
Taiwan	26	28	28
United Kingdom	1	4	0
United States	58	58	60
Duration of Rheumatoid Arthritis			
n= 228, 225, 225 and 678			
Units: years			
arithmetic mean	7.2	7.6	7.7
standard deviation	± 7.5	± 7.6	± 7.9
Tender Joint Count of 68 Evaluable Joints			
Units: Number of Joints			
arithmetic mean	24.3	23.5	24.3
standard deviation	± 15	± 14.1	± 14
Swollen Joint Count of 66 Evaluable Joints			
Units: Number of Joints			
arithmetic mean	13.1	13.6	13.5
standard deviation	± 7.2	± 8.7	± 6.9
High Sensitivity C-Reactive Protein (hsCRP)			
Units: milligram per Liter (mg/L)			
arithmetic mean	17.7	18.2	14.2
standard deviation	± 20.4	± 21.5	± 14.5

Reporting group values	Total		
Number of subjects	684		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	587		
From 65-84 years	97		
85 years and over	0		
Age Continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender, Male/Female Units: participants			
Female	560		
Male	124		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	44		
Not Hispanic or Latino	131		
Unknown or Not Reported	509		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	14		
Asian	180		
Native Hawaiian or Other Pacific Islander	1		
Black or African American	28		
White	457		
More than one race	3		
Unknown or Not Reported	1		
Region of Enrollment Units: Subjects			
Argentina	64		
Australia	15		
Belgium	11		
Canada	28		
Croatia	4		
Czech Republic	15		
Germany	9		
Hungary	20		
India	58		
Italy	10		
Japan	21		

Korea, Republic of	17		
Mexico	22		
Poland	51		
Portugal	5		
Romania	6		
Russian Federation	20		
Slovakia	11		
Spain	34		
Taiwan	82		
United Kingdom	5		
United States	176		
Duration of Rheumatoid Arthritis			
n= 228, 225, 225 and 678			
Units: years			
arithmetic mean			
standard deviation	-		
Tender Joint Count of 68 Evaluable Joints			
Units: Number of Joints			
arithmetic mean			
standard deviation	-		
Swollen Joint Count of 66 Evaluable Joints			
Units: Number of Joints			
arithmetic mean			
standard deviation	-		
High Sensitivity C-Reactive Protein (hsCRP)			
Units: milligram per Liter (mg/L)			
arithmetic mean			
standard deviation	-		

End points

End points reporting groups

Reporting group title	Placebo
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Reporting group description:

Placebo administered orally (PO) once daily (QD) through Week 24. Participants continued to take background conventional disease-modifying antirheumatic drug (cDMARD) therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD.

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

Reporting group title	Baricitinib 2 mg
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Reporting group description:

Baricitinib 2 mg PO QD through Week 24. Participants continued to take background cDMARD therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD.

Reporting group title	Baricitinib 4 mg
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Reporting group description:

Baricitinib 4 mg PO QD through Week 24. Participants continued to take background cDMARD therapy throughout study. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg PO, QD.

Reporting group title	Placebo-Follow Up
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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
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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
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Reporting group description:

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

Includes participants who were rescued to Baricitinib 4 mg.

Subject analysis set title	PK population 2 mg Baricitinib
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Subject analysis set type	Sub-group analysis
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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 4 mg Baricitinib
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Subject analysis set type	Sub-group analysis
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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% Improvement (ACR20)

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

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

Analysis Population Description: 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	228	229	227	
Units: percentage of participants				
number (not applicable)	39.5	65.9	61.7	

Statistical analyses

Statistical analysis title	Statistical Analysis for ACR20
Comparison groups	Baricitinib 4 mg v Placebo
Number of subjects included in analysis	455
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Regression, Logistic

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

End point title	Change from Baseline in the Health Assessment Questionnaire-Disability Index (HAQ-DI) Score
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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: 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	228	229	227	
Units: units on a scale				
arithmetic mean (standard deviation)	-0.3 (± 0.45)	-0.52 (± 0.59)	-0.52 (± 0.6)	

Statistical analyses

No statistical analyses for this end point

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

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

Disease Activity Score (DAS) modified to include 28 joint count (DAS28) consisted of composite score of following variables: tender joint count (TJC28), swollen joint count (SJC28), C-reactive protein (CRP) (milligrams per liter), and Patient's Global Assessment of Disease Activity using visual analog scale (VAS) (participant global VAS). DAS28 was calculated using following formula: $\text{DAS28-CRP} = 0.56 \times \sqrt{\text{TJC28}} + 0.28 \times \sqrt{\text{SJC28}} + 0.36 \times \ln(\text{CRP} + 1) + 0.014 \times \text{Patient's Global VAS} + 0.96$. Scores ranged 1.0-9.4, where lower scores indicated less disease activity.

Analysis Population Description 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	228	229	227	
Units: units on a scale				
arithmetic mean (standard deviation)	-1.05 (± 1.23)	-1.83 (± 1.22)	-1.91 (± 1.21)	

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Participants Achieving Simplified Disease Activity Index (SDAI) ≤3.3
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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 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	228	229	227	
Units: percentage of participants				
number (not applicable)	0.9	9.2	8.8	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Duration of Morning Joint Stiffness (MJS) in the Prior 7 Days as Collected in Electronic Daily Diaries

End point title	Mean Duration of Morning Joint Stiffness (MJS) in the Prior 7 Days as Collected in Electronic Daily Diaries
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End point description:

Participants reported the duration of their morning joint stiffness (MJS) in hours and minutes into daily electronic diaries. If MJS duration was longer than 12 hours (720 minutes), it was truncated to 720 minutes for statistical presentations and analyses. The average value across the 7 days preceding each visit is calculated. A decrease in duration of MJS indicated an improvement in the participant's condition.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug and had at least 4 entries within any post-baseline 7-day window are included in the analysis.

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	221	223	222	
Units: minutes				
median (confidence interval 95%)	60 (50.7 to 76.7)	44.4 (30 to 60)	34.6 (23.7 to 51.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Severity of Morning Joint Stiffness Numeric Rating Scale (NRS) in the Prior 7 Days as Collected in Electronic Diaries

End point title	Mean Severity of Morning Joint Stiffness Numeric Rating Scale (NRS) in the Prior 7 Days as Collected in Electronic Diaries
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End point description:

Participants rated the severity of their MJS by selecting a number from 0 to 10 that best described their overall level of MJS from the time they woke up, where 0 represents "no joint stiffness" and 10 represents "joint stiffness as bad as you can imagine". Participants reported their severity daily in electronic diaries. The average value across the 7 days preceding each visit is calculated. A decrease in severity rating indicated an improvement in the participant's condition.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug and had at least 4 entries within any post-baseline 7-day window are included in the analysis.

End point type	Secondary
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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	221	223	222	
Units: units on a scale				
arithmetic mean (standard deviation)	4.2 (± 2.3)	3.5 (± 2.5)	3.4 (± 2.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Worst Tiredness Numeric Rating Scale (NRS) in the Prior 7 Days as Collected in Electronic Diaries

End point title	Mean Worst Tiredness Numeric Rating Scale (NRS) in the Prior 7 Days as Collected in Electronic Diaries
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End point description:

Participants rated their tiredness by selecting a number from 0 to 10 that best described their level of worst tiredness during the past 24 hours, where 0 represents "no tiredness" and 10 represents "as bad as you can imagine". Participants reported their worst tiredness in daily electronic diaries. The average value across the 7 days preceding each visit is calculated. A decrease in tiredness severity rating indicated an improvement in the participant's condition.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug and had at least 4 entries within any post-baseline 7-day window are included in the analysis.

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	221	223	222	
Units: units on a scale				
arithmetic mean (standard deviation)	4.5 (± 2.2)	4 (± 2.5)	4 (± 2.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Worst Joint Pain Numeric Rating Scale (NRS) in the Prior 7 days as Collected in Electronic Diaries

End point title	Mean Worst Joint Pain Numeric Rating Scale (NRS) in the Prior 7 days as Collected in Electronic Diaries
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End point description:

Participants rated their joint pain by selecting a number from 0 to 10 that best described their worst joint pain during the last 24 hours, where 0 represents "no pain" and 10 represents "pain as bad as you can imagine". Participants reported their worst joint pain in daily electronic diaries. The average value across the 7 days preceding each visit is calculated. A decrease in joint pain severity rating indicated an improvement in the participant's condition.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug and had at least 4 entries within any post-baseline 7-day window are included in the analysis.

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	221	223	222	
Units: units on a scale				
arithmetic mean (standard deviation)	4.7 (± 2.2)	3.9 (± 2.5)	3.8 (± 2.2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving American College of Rheumatology

50% (ACR50) Response

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

ACR50 Responder Index is composite of clinical, laboratory, and functional measures in RA. "ACR50 Responder" is a participant who has at least 50% improvement in both tender and swollen joint counts and in at least 3 of the following 5 criteria:

Physician's Global Assessment of Disease Activity, Patient's Global Assessment of Disease Activity, HAQ-DI, participant's assessment of pain, and hsCRP. Participants with missing responses and participants who discontinue study or drug or are rescued before analysis timepoint are deemed non-responders.

Analysis Population Description: 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
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End point timeframe:

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	228	229	227	
Units: percentage of participants				
number (not applicable)				
Week 12	12.7	33.6	33.5	
Week 24	21.5	41.5	44.1	

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
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End point description:

ACR70 Responder Index is composite of clinical, laboratory, and functional measures in RA. "ACR70 Responder" is a participant who has at least 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, participant's assessment of pain, and 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: 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
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End point timeframe:

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	228	229	227	
Units: percentage of participants				
number (not applicable)				
Week 12	3.1	17.9	18.1	
Week 24	7.9	25.3	24.2	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Measures of Clinical Disease Activity Index (CDAI) Score

End point title	Change From Baseline in Measures of Clinical Disease Activity Index (CDAI) Score
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End point description:

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

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

End point type	Secondary
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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	218	224	219	
Units: units on a scale				
arithmetic mean (standard deviation)	-14.29 (± 16.04)	-20.99 (± 14.48)	-23.18 (± 13.47)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Measures of Simplified Disease Activity Index (SDAI) Score

End point title	Change from Baseline in Measures of Simplified Disease Activity Index (SDAI) Score
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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: All randomized participants who received at least 1 dose of the study drug, with a baseline value and at least 1 post-baseline value. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mLOCF.

End point type	Secondary
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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	218	224	219	
Units: units on a scale				
arithmetic mean (standard deviation)	-14.55 (± 16.37)	-21.87 (± 14.99)	-23.78 (± 13.94)	

Statistical analyses

No statistical analyses for this end point

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

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

DAS28 consisted of composite score of following variables: tender joint count (TJC28), swollen joint count (SJC28), Erythrocyte Sedimentation Rate (ESR) (millimeters per hour), and Patient's Global Assessment of Disease Activity. DAS28 was calculated using following formula: $\text{DAS28-ESR} = 0.56 \times \sqrt{\text{TJC28}} + 0.28 \times \sqrt{\text{SJC28}} + 0.70 \times \ln(\text{ESR}) + 0.014 \times \text{Patient's Global VAS}$. Scores ranged 1.0-9.4, where lower scores indicated less disease activity.

Analysis Population Description: 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
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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	220	226	221	
Units: units on a scale				
arithmetic mean (standard deviation)	-1.16 (± 1.27)	-1.89 (± 1.23)	-1.97 (± 1.16)	

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of Participants Achieving American College of Rheumatology European League Against Rheumatism (ACR/EULAR) Remission – Boolean Remission
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End point description:

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

Analysis Population Description: 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
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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	228	229	227	
Units: percentage of participants				
number (not applicable)	0.4	7	6.6	

Statistical analyses

No statistical analyses for this end point

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

End point title	Change from Baseline in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) Scores.
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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: All randomized participants who received at least 1 dose of the study drug, with a baseline value and at least 1 post-baseline value. Missing values due to discontinuation of study or drug, rescue, or missing data were imputed using mLOCF.

End point type	Secondary
End point timeframe:	
Baseline, Week 12; 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	216	227	216	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 12	7.6 (± 10.3)	8.7 (± 11.1)	8.8 (± 10.6)	
Week 24	7.8 (± 11)	9.2 (± 10.7)	9.7 (± 10.8)	

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)
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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, as well as 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 or functioning.

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

End point type	Secondary
End point timeframe:	
Baseline, Week 12; 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	218	229	219	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 12, MCS	3.3 (± 10.6)	3.6 (± 10.5)	3.3 (± 11)	
Week 24, MCS	2.7 (± 11.5)	3 (± 10.4)	3.3 (± 11.3)	
Week 12, PCS	4.1 (± 7.3)	7.7 (± 8.5)	7 (± 8.3)	
Week 24, PCS	4.9 (± 8)	8.5 (± 9)	8.6 (± 9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in European Quality of Life-5 Dimensions-5 Level (EQ-5D-5L) Scores

End point title	Change from Baseline in European Quality of Life-5 Dimensions-5 Level (EQ-5D-5L) Scores
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End point description:

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

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

End point type	Secondary
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End point timeframe:

Baseline Week 12; 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	216	227	216	
Units: units on a scale				
arithmetic mean (standard deviation)				
Index Score (US Algorithm) Week 12	0.054 (± 0.155)	0.117 (± 0.151)	0.109 (± 0.165)	
Index Score (US Algorithm) Week 24	0.051 (± 0.149)	0.113 (± 0.172)	0.129 (± 0.173)	
Index Score (UK Algorithm) Week 12	0.074 (± 0.23)	0.167 (± 0.221)	0.159 (± 0.237)	
Index Score (UK Algorithm) Week 24	0.075 (± 0.218)	0.162 (± 0.254)	0.185 (± 0.25)	

Statistical analyses

No statistical analyses for this end point

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

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

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

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

End point type	Secondary
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End point timeframe:

Baseline Week 12; 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	216	227	216	
Units: mm				
arithmetic mean (standard deviation)				
Self-Perceived Health, Week 12	5.7 (± 23.8)	13.4 (± 21.8)	11.5 (± 25.2)	
Self-Perceived Health, Week 24	8.4 (± 25.1)	13.1 (± 25.8)	10.4 (± 28.9)	

Statistical analyses

No statistical analyses for this end point

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

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

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

four types of scores: Absenteeism (work time missed), Presenteeism (impairment at work), Work productivity loss (overall work impairment), and Activity impairment.

Analysis Population Description: All randomized participants who received at least 1 dose of the study drug. Change from baseline includes participants with a baseline value and an observed value at the time point being summarized.

End point type	Secondary
End point timeframe:	
Baseline, Week 12; 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	228	229	227	
Units: percentage of impairment				
arithmetic mean (standard deviation)				
Absenteeism Week 12 (n= 73,72,69)	2.6 (± 23.5)	-6.3 (± 26.5)	2.5 (± 24.7)	
Absenteeism Week 24 (n= 44,62,56)	-2.1 (± 13.9)	-3.8 (± 28.2)	4 (± 27.2)	
Presenteeism Week 12 (n= 71, 69, 66)	-8 (± 26)	-17 (± 25)	-15 (± 27)	
Presenteeism Week 24 (n= 44,61,53)	-17 (± 26)	-20 (± 23)	-17 (± 21)	
Work Productivity Loss Week 12 (n= 71,69,66)	-4.2 (± 27.7)	-17.6 (± 30.4)	-9.9 (± 23.7)	
Work Productivity Loss Week 24 (n= 44,61,53)	-15.9 (± 26.1)	-19.6 (± 25)	-14.3 (± 23)	
Activity Impairment Week 12(n=206, 222, 213)	-13 (± 25)	-19 (± 27)	-19 (± 25)	
Activity Impairment Week 24 (n= 141,187,187)	-18 (± 27)	-23 (± 28)	-21 (± 27)	

Statistical analyses

No statistical analyses for this end point

Secondary: Population Pharmacokinetics (PK): Maximum Concentration at Steady State of Dosing (C_{max,ss}) of LY3009104

End point title	Population Pharmacokinetics (PK): Maximum Concentration at Steady State of Dosing (C _{max,ss}) of LY3009104
End point description:	
End point type	Secondary
End point timeframe:	
Week 0: 30 and 90 minutes postdose; Week 8: 1 hour postdose; Week 12, Week 20 and Week 24:predose	

End point values	PK population 2 mg Baricitinib	PK Population 4 mg Baricitinib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	246	245		
Units: nanogram per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)	70.2 (± 26.2)	138 (± 25.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Population PK: Maximum Concentration at Steady State of Dosing (AUC_{ss}) of LY3009104

End point title	Population PK: Maximum Concentration at Steady State of Dosing (AUC _{ss}) of LY3009104
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End point description:

End point type	Secondary
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End point timeframe:

Week 0: 30 and 90 minutes postdose; Week 8: 1 hour postdose; Week 12, Week 20 and Week 24; predose

End point values	PK population 2 mg Baricitinib	PK Population 4 mg Baricitinib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	246	245		
Units: nanograms per mL per hour (ng/mL*h)				
geometric mean (geometric coefficient of variation)	637 (± 44.5)	1210 (± 47)		

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-JADX

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	17.1
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Reporting groups

Reporting group title	PLACEBO
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Reporting group description: -

Reporting group title	Baricitinib 2 mg
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Reporting group description: -

Reporting group title	Baricitinib 4 mg
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Reporting group description: -

Reporting group title	Rescue
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Reporting group description: -

Reporting group title	Placebo- Follow Up
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Reporting group description: -

Reporting group title	Baricitinib 2 mg – Follow Up
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Reporting group description: -

Reporting group title	Baricitinib 4 mg – Follow Up
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Reporting group description: -

Serious adverse events	PLACEBO	Baricitinib 2 mg	Baricitinib 4 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 228 (5.70%)	6 / 229 (2.62%)	12 / 227 (5.29%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
animal bite			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	2 / 228 (0.88%)	0 / 229 (0.00%)	0 / 227 (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
patella fracture alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (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
tibia fracture alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
upper limb fracture alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
angina pectoris alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	0 / 227 (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
myocardial infarction alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (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
ventricular tachycardia alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (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			
migraine alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	0 / 227 (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
subarachnoid haemorrhage alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Blood and lymphatic system disorders			
anaemia alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
diverticulum intestinal alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (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
dyspepsia alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal haemorrhage alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (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
Respiratory, thoracic and mediastinal disorders			
acute respiratory distress syndrome alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	0 / 227 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
acute respiratory failure alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	0 / 227 (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
allergic bronchitis alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
interstitial lung disease alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pleural effusion alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis acute			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
psoriasis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	0 / 227 (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
rash pruritic			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
subcutaneous emphysema			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (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			
depression			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (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
post-traumatic stress disorder alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	0 / 227 (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
suicidal ideation alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (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
Renal and urinary disorders			
renal failure alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
back pain alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (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
muscular weakness alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myalgia alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myositis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
polymyositis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	0 / 227 (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 17.1			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (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
spinal pain			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial cyst			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (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
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	0 / 227 (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
bacterial infection			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	0 / 227 (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
disseminated tuberculosis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
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			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	1 / 229 (0.44%)	0 / 227 (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 respiratory tract infection			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pelvic abscess			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	0 / 227 (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 17.1			
subjects affected / exposed	2 / 228 (0.88%)	1 / 229 (0.44%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 2	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (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
viral infection			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	1 / 227 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
wound infection staphylococcal			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 228 (0.44%)	0 / 229 (0.00%)	0 / 227 (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

Serious adverse events	Rescue	Placebo- Follow Up	Baricitinib 2 mg – Follow Up
Total subjects affected by serious adverse events			

subjects affected / exposed	1 / 91 (1.10%)	1 / 17 (5.88%)	0 / 19 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
animal bite			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
patella fracture			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tibia fracture			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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 limb fracture			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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			
angina pectoris			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
atrial fibrillation			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
ventricular tachycardia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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			
migraine			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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			
anaemia			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
dyspepsia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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 haemorrhage			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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			
acute respiratory distress syndrome			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
acute respiratory failure			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
allergic bronchitis			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
interstitial lung disease alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
pleural effusion alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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 acute alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
Skin and subcutaneous tissue disorders			
psoriasis alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
rash pruritic alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
subcutaneous emphysema alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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			
depression alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
post-traumatic stress disorder alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
suicidal ideation alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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			
back pain alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
muscular weakness			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
myalgia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
myositis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
polymyositis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 17 (5.88%)	0 / 19 (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
rheumatoid arthritis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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 pain			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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

synovial cyst alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 91 (0.00%) 0 / 0 0 / 0	 0 / 17 (0.00%) 0 / 0 0 / 0	 0 / 19 (0.00%) 0 / 0 0 / 0
Infections and infestations			
appendicitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 91 (0.00%) 0 / 0 0 / 0	 1 / 17 (5.88%) 0 / 1 0 / 0	 0 / 19 (0.00%) 0 / 0 0 / 0
bacterial infection alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 91 (0.00%) 0 / 0 0 / 0	 0 / 17 (0.00%) 0 / 0 0 / 0	 0 / 19 (0.00%) 0 / 0 0 / 0
bronchitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 91 (0.00%) 0 / 0 0 / 0	 0 / 17 (0.00%) 0 / 0 0 / 0	 0 / 19 (0.00%) 0 / 0 0 / 0
cellulitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 1 / 91 (1.10%) 1 / 1 0 / 0	 0 / 17 (0.00%) 0 / 0 0 / 0	 0 / 19 (0.00%) 0 / 0 0 / 0
disseminated tuberculosis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	 0 / 91 (0.00%) 0 / 0 0 / 0	 0 / 17 (0.00%) 0 / 0 0 / 0	 0 / 19 (0.00%) 0 / 0 0 / 0
gastroenteritis alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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 respiratory tract infection alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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
pelvic abscess alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 17 (5.88%)	0 / 19 (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 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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 17.1			
subjects affected / exposed	1 / 91 (1.10%)	0 / 17 (0.00%)	0 / 19 (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
viral infection alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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

wound infection staphylococcal alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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	1 / 22 (4.55%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
animal bite			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
fall			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
patella fracture			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
tibia fracture			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
upper limb fracture			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
atrial fibrillation			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
myocardial infarction			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
ventricular tachycardia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
migraine			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
subarachnoid haemorrhage			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
diverticulum intestinal			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
dyspepsia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
acute respiratory distress syndrome			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
acute respiratory failure			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
allergic bronchitis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
interstitial lung disease			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pleural effusion			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pulmonary embolism			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
cholecystitis acute			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
psoriasis			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
rash pruritic			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
subcutaneous emphysema			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
post-traumatic stress disorder			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
suicidal ideation			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (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 17.1			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
muscular weakness			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
myalgia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
myositis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
polymyositis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
rheumatoid arthritis			
alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
spinal pain				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
synovial cyst				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
appendicitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bacterial infection				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bronchitis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cellulitis				
alternative dictionary used: MedDRA 17.1				

subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
disseminated tuberculosis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastroenteritis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
lower respiratory tract infection				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pelvic abscess				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonia				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 22 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sepsis				
alternative dictionary used: MedDRA 17.1				
subjects affected / exposed	0 / 22 (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 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 22 (0.00%) 0 / 0 0 / 0			
viral infection alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 22 (0.00%) 0 / 0 0 / 0			
wound infection staphylococcal alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	0 / 22 (0.00%) 0 / 0 0 / 0			

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	105 / 228 (46.05%)	108 / 229 (47.16%)	127 / 227 (55.95%)
Vascular disorders hypertension alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	2 / 228 (0.88%) 2	10 / 229 (4.37%) 10	6 / 227 (2.64%) 6
General disorders and administration site conditions fatigue alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) oedema peripheral alternative dictionary used: MedDRA 17.1	5 / 228 (2.19%) 5	2 / 229 (0.87%) 3	5 / 227 (2.20%) 5

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>pyrexia</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>6 / 228 (2.63%)</p> <p>6</p> <p>2 / 228 (0.88%)</p> <p>2</p>	<p>3 / 229 (1.31%)</p> <p>3</p> <p>1 / 229 (0.44%)</p> <p>1</p>	<p>3 / 227 (1.32%)</p> <p>3</p> <p>5 / 227 (2.20%)</p> <p>7</p>
<p>Reproductive system and breast disorders</p> <p>erectile dysfunction</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed^[1]</p> <p>occurrences (all)</p> <p>vulvovaginal pruritus</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed^[2]</p> <p>occurrences (all)</p>	<p>0 / 39 (0.00%)</p> <p>0</p> <p>0 / 189 (0.00%)</p> <p>0</p>	<p>0 / 45 (0.00%)</p> <p>0</p> <p>0 / 184 (0.00%)</p> <p>0</p>	<p>1 / 40 (2.50%)</p> <p>1</p> <p>0 / 187 (0.00%)</p> <p>0</p>
<p>Respiratory, thoracic and mediastinal disorders</p> <p>cough</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>dyspnoea</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>oropharyngeal pain</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>3 / 228 (1.32%)</p> <p>4</p> <p>0 / 228 (0.00%)</p> <p>0</p> <p>2 / 228 (0.88%)</p> <p>2</p>	<p>9 / 229 (3.93%)</p> <p>11</p> <p>0 / 229 (0.00%)</p> <p>0</p> <p>4 / 229 (1.75%)</p> <p>4</p>	<p>9 / 227 (3.96%)</p> <p>10</p> <p>0 / 227 (0.00%)</p> <p>0</p> <p>9 / 227 (3.96%)</p> <p>9</p>
<p>Psychiatric disorders</p> <p>depression</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>7 / 228 (3.07%)</p> <p>7</p>	<p>0 / 229 (0.00%)</p> <p>0</p>	<p>1 / 227 (0.44%)</p> <p>1</p>
Investigations			

alanine aminotransferase increased alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	2 / 228 (0.88%) 3	5 / 229 (2.18%) 6	5 / 227 (2.20%) 6
aspartate aminotransferase increased alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	1 / 228 (0.44%) 2	3 / 229 (1.31%) 3	6 / 227 (2.64%) 7
blood creatine phosphokinase increased alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 228 (0.00%) 0	8 / 229 (3.49%) 8	15 / 227 (6.61%) 17
Cardiac disorders sinus bradycardia alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 228 (0.00%) 0	0 / 229 (0.00%) 0	0 / 227 (0.00%) 0
Nervous system disorders dizziness alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) headache alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	4 / 228 (1.75%) 4 8 / 228 (3.51%) 10	3 / 229 (1.31%) 3 15 / 229 (6.55%) 17	7 / 227 (3.08%) 9 9 / 227 (3.96%) 10
Blood and lymphatic system disorders anaemia alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	6 / 228 (2.63%) 6	6 / 229 (2.62%) 6	4 / 227 (1.76%) 4
Gastrointestinal disorders abdominal pain alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 228 (0.00%)	5 / 229 (2.18%)	3 / 227 (1.32%)
occurrences (all)	0	5	3
abdominal pain upper			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 228 (0.44%)	5 / 229 (2.18%)	4 / 227 (1.76%)
occurrences (all)	1	5	4
constipation			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	3 / 228 (1.32%)	7 / 229 (3.06%)	5 / 227 (2.20%)
occurrences (all)	4	7	5
diarrhoea			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	10 / 228 (4.39%)	10 / 229 (4.37%)	4 / 227 (1.76%)
occurrences (all)	11	11	5
dyspepsia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 228 (0.88%)	1 / 229 (0.44%)	5 / 227 (2.20%)
occurrences (all)	2	1	5
gastritis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	0 / 227 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	5 / 228 (2.19%)	2 / 229 (0.87%)	1 / 227 (0.44%)
occurrences (all)	5	2	1
lip disorder			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	0 / 229 (0.00%)	0 / 227 (0.00%)
occurrences (all)	0	0	0
mouth ulceration			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 228 (0.00%)	5 / 229 (2.18%)	3 / 227 (1.32%)
occurrences (all)	0	6	3

nausea alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	8 / 228 (3.51%) 9	7 / 229 (3.06%) 7	5 / 227 (2.20%) 5
vomiting alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	4 / 228 (1.75%) 5	7 / 229 (3.06%) 7	4 / 227 (1.76%) 4
Skin and subcutaneous tissue disorders acne alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 228 (0.00%) 0	0 / 229 (0.00%) 0	0 / 227 (0.00%) 0
alopecia alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	4 / 228 (1.75%) 4	1 / 229 (0.44%) 1	6 / 227 (2.64%) 6
dermatitis bullous alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 228 (0.00%) 0	0 / 229 (0.00%) 0	0 / 227 (0.00%) 0
Musculoskeletal and connective tissue disorders arthralgia alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	3 / 228 (1.32%) 3	6 / 229 (2.62%) 8	6 / 227 (2.64%) 6
back pain alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	10 / 228 (4.39%) 10	9 / 229 (3.93%) 9	5 / 227 (2.20%) 5
Infections and infestations bronchitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	11 / 228 (4.82%) 12	6 / 229 (2.62%) 7	7 / 227 (3.08%) 8

gastroenteritis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	1 / 228 (0.44%) 1	4 / 229 (1.75%) 4	9 / 227 (3.96%) 9
nasopharyngitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	18 / 228 (7.89%) 19	10 / 229 (4.37%) 10	18 / 227 (7.93%) 22
pharyngitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	3 / 228 (1.32%) 3	6 / 229 (2.62%) 6	8 / 227 (3.52%) 8
rash pustular alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 228 (0.00%) 0	0 / 229 (0.00%) 0	0 / 227 (0.00%) 0
sinusitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	6 / 228 (2.63%) 6	3 / 229 (1.31%) 3	4 / 227 (1.76%) 4
upper respiratory tract infection alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	18 / 228 (7.89%) 19	14 / 229 (6.11%) 16	24 / 227 (10.57%) 26
urinary tract infection alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	4 / 228 (1.75%) 5	12 / 229 (5.24%) 13	9 / 227 (3.96%) 9
Metabolism and nutrition disorders hypercholesterolaemia alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	2 / 228 (0.88%) 2	5 / 229 (2.18%) 5	9 / 227 (3.96%) 9
hyperlipidaemia alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	2 / 228 (0.88%)	2 / 229 (0.87%)	6 / 227 (2.64%)
occurrences (all)	2	2	6

Non-serious adverse events	Rescue	Placebo- Follow Up	Baricitinib 2 mg – Follow Up
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 91 (23.08%)	2 / 17 (11.76%)	0 / 19 (0.00%)
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
erectile dysfunction			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed ^[1]	0 / 13 (0.00%)	0 / 6 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
vulvovaginal pruritus			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed ^[2]	0 / 78 (0.00%)	1 / 11 (9.09%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			

cough alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 17 (0.00%) 0	0 / 19 (0.00%) 0
dyspnoea alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 17 (0.00%) 0	0 / 19 (0.00%) 0
oropharyngeal pain alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	3 / 91 (3.30%) 3	0 / 17 (0.00%) 0	0 / 19 (0.00%) 0
Psychiatric disorders depression alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 17 (0.00%) 0	0 / 19 (0.00%) 0
Investigations alanine aminotransferase increased alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 17 (0.00%) 0	0 / 19 (0.00%) 0
aspartate aminotransferase increased alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 17 (0.00%) 0	0 / 19 (0.00%) 0
blood creatine phosphokinase increased alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	1 / 17 (5.88%) 1	0 / 19 (0.00%) 0
Cardiac disorders sinus bradycardia alternative dictionary used: MedDRA 17.1			

subjects affected / exposed occurrences (all)	0 / 91 (0.00%) 0	0 / 17 (0.00%) 0	0 / 19 (0.00%) 0
Nervous system disorders dizziness alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) headache alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	 0 / 91 (0.00%) 0 3 / 91 (3.30%) 3	 0 / 17 (0.00%) 0 0 / 17 (0.00%) 0	 0 / 19 (0.00%) 0 0 / 19 (0.00%) 0
Blood and lymphatic system disorders anaemia alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	 0 / 91 (0.00%) 0	 0 / 17 (0.00%) 0	 0 / 19 (0.00%) 0
Gastrointestinal disorders abdominal pain alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) abdominal pain upper alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) constipation alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) diarrhoea alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) dyspepsia alternative dictionary used: MedDRA 17.1	 0 / 91 (0.00%) 0 0 / 91 (0.00%) 0 0 / 91 (0.00%) 0 2 / 91 (2.20%) 2 	 0 / 17 (0.00%) 0 0 / 17 (0.00%) 0 0 / 17 (0.00%) 0 1 / 17 (5.88%) 1 	 0 / 19 (0.00%) 0 0 / 19 (0.00%) 0 0 / 19 (0.00%) 0 0 / 19 (0.00%) 0

subjects affected / exposed	2 / 91 (2.20%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
gastritis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 91 (2.20%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
lip disorder			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
mouth ulceration			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 91 (2.20%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 91 (2.20%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
alopecia			
alternative dictionary used: MedDRA 17.1			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>dermatitis bullous</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 91 (0.00%)</p> <p>0</p> <p>0 / 91 (0.00%)</p> <p>0</p>	<p>0 / 17 (0.00%)</p> <p>0</p> <p>1 / 17 (5.88%)</p> <p>1</p>	<p>0 / 19 (0.00%)</p> <p>0</p> <p>0 / 19 (0.00%)</p> <p>0</p>
<p>Musculoskeletal and connective tissue disorders</p> <p>arthralgia</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>back pain</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 91 (0.00%)</p> <p>0</p> <p>0 / 91 (0.00%)</p> <p>0</p>	<p>0 / 17 (0.00%)</p> <p>0</p> <p>0 / 17 (0.00%)</p> <p>0</p>	<p>0 / 19 (0.00%)</p> <p>0</p> <p>0 / 19 (0.00%)</p> <p>0</p>
<p>Infections and infestations</p> <p>bronchitis</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>gastroenteritis</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>nasopharyngitis</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>pharyngitis</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>rash pustular</p> <p>alternative dictionary used: MedDRA 17.1</p>	<p>2 / 91 (2.20%)</p> <p>2</p> <p>0 / 91 (0.00%)</p> <p>0</p> <p>0 / 91 (0.00%)</p> <p>0</p> <p>0 / 91 (0.00%)</p> <p>0</p>	<p>0 / 17 (0.00%)</p> <p>0</p> <p>0 / 17 (0.00%)</p> <p>0</p> <p>0 / 17 (0.00%)</p> <p>0</p> <p>0 / 17 (0.00%)</p> <p>0</p>	<p>0 / 19 (0.00%)</p> <p>0</p> <p>0 / 19 (0.00%)</p> <p>0</p> <p>0 / 19 (0.00%)</p> <p>0</p> <p>0 / 19 (0.00%)</p> <p>0</p>

subjects affected / exposed	0 / 91 (0.00%)	1 / 17 (5.88%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
sinusitis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	2 / 91 (2.20%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
urinary tract infection			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	3 / 91 (3.30%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	3	0	0
Metabolism and nutrition disorders			
hypercholesterolaemia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	4 / 91 (4.40%)	0 / 17 (0.00%)	0 / 19 (0.00%)
occurrences (all)	4	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 91 (0.00%)	0 / 17 (0.00%)	0 / 19 (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	4 / 22 (18.18%)		
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
fatigue			
alternative dictionary used: MedDRA 17.1			

<p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>oedema peripheral</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>pyrexia</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Reproductive system and breast disorders</p> <p>erectile dysfunction</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed^[1]</p> <p>0 / 3 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>vulvovaginal pruritus</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed^[2]</p> <p>0 / 19 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Respiratory, thoracic and mediastinal disorders</p> <p>cough</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>1 / 22 (4.55%)</p> <p>occurrences (all)</p> <p>1</p> <p>dyspnoea</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>1 / 22 (4.55%)</p> <p>occurrences (all)</p> <p>1</p> <p>oropharyngeal pain</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
Psychiatric disorders			

depression alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
Investigations alanine aminotransferase increased alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) aspartate aminotransferase increased alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) blood creatine phosphokinase increased alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0 0 / 22 (0.00%) 0 0 / 22 (0.00%) 0		
Cardiac disorders sinus bradycardia alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	1 / 22 (4.55%) 1		
Nervous system disorders dizziness alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all) headache alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0 0 / 22 (0.00%) 0		
Blood and lymphatic system disorders anaemia alternative dictionary used: MedDRA 17.1			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
abdominal pain			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
abdominal pain upper			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
constipation			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
diarrhoea			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
dyspepsia			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
gastritis			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	1 / 22 (4.55%)		
occurrences (all)	1		
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 17.1			
subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
lip disorder			
alternative dictionary used: MedDRA 17.1			

<p>subjects affected / exposed</p> <p>1 / 22 (4.55%)</p> <p>occurrences (all)</p> <p>1</p>			
<p>mouth ulceration</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>nausea</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>vomiting</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Skin and subcutaneous tissue disorders</p> <p>acne</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>alopecia</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>dermatitis bullous</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Musculoskeletal and connective tissue disorders</p> <p>arthralgia</p> <p>alternative dictionary used: MedDRA 17.1</p> <p>subjects affected / exposed</p> <p>0 / 22 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>back pain</p> <p>alternative dictionary used: MedDRA 17.1</p>			

subjects affected / exposed	0 / 22 (0.00%)		
occurrences (all)	0		
Infections and infestations bronchitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
gastroenteritis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
nasopharyngitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
pharyngitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
rash pustular alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
sinusitis alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
upper respiratory tract infection alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
urinary tract infection alternative dictionary used: MedDRA 17.1			

subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
Metabolism and nutrition disorders hypercholesterolaemia alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		
hyperlipidaemia alternative dictionary used: MedDRA 17.1 subjects affected / exposed occurrences (all)	0 / 22 (0.00%) 0		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

[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.

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

None reported

Notes: