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

Summary

EudraCT number	2012-002322-73
Trial protocol	HU GR BE LV GB DE PT CZ NL LT SK ES SI
Global end of trial date	29 September 2015

Results information

Result version number	v2 (current)
This version publication date	04 August 2017
First version publication date	26 March 2017
Version creation reason	• New data added to full data set • Correction of full data set Revision required

Trial information

Trial identification

Sponsor protocol code	13978

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01710358
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 13978, Trial Alias: I4V-MC-JADV

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	29 September 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 September 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to determine whether baricitinib is superior to placebo in the treatment of participants with moderately to severely active Rheumatoid Arthritis (RA) who have had an inadequate response to methotrexate (MTX) treatment.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 October 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: 255
Country: Number of subjects enrolled	Belgium: 8
Country: Number of subjects enrolled	Canada: 11
Country: Number of subjects enrolled	China: 54
Country: Number of subjects enrolled	Croatia: 1
Country: Number of subjects enrolled	Czech Republic: 36
Country: Number of subjects enrolled	France: 23
Country: Number of subjects enrolled	Germany: 2
Country: Number of subjects enrolled	Greece: 3
Country: Number of subjects enrolled	Hungary: 37
Country: Number of subjects enrolled	Japan: 249
Country: Number of subjects enrolled	Korea, Republic of: 57
Country: Number of subjects enrolled	Latvia: 9
Country: Number of subjects enrolled	Lithuania: 26
Country: Number of subjects enrolled	Mexico: 125
Country: Number of subjects enrolled	Poland: 80
Country: Number of subjects enrolled	Portugal: 3
Country: Number of subjects enrolled	Romania: 16
Country: Number of subjects enrolled	Russian Federation: 78

Country: Number of subjects enrolled	Slovakia: 20
Country: Number of subjects enrolled	Slovenia: 5
Country: Number of subjects enrolled	South Africa: 56
Country: Number of subjects enrolled	Spain: 31
Country: Number of subjects enrolled	Taiwan: 18
Country: Number of subjects enrolled	United Kingdom: 8
Country: Number of subjects enrolled	United States: 94
Worldwide total number of subjects	1305
EEA total number of subjects	308

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)	1064
From 65 to 84 years	240
85 years and over	1

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. Participants not rescued at Week 16 may be rescued at the discretion of the investigator anytime thereafter.

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

Period 1

Period 1 title	Treatment Period Part A (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. At Week 24, participants were given baricitinib 4 milligram (mg) orally once daily through Week 52. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily through Week 52. Participants continued to take background methotrexate (MTX) therapy throughout study.

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

"Not completed" participants include participants who were rescued during Part A and discontinued study during Part B.

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 once daily through Week 24.

Investigational medicinal product name	Adalimumab Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Adalimumab placebo administered by SC injection every 2 weeks through Week 50.

Arm title	Baricitinib

Arm description:

Baricitinib 4 mg administered orally once daily through Week 52 and an adalimumab placebo by subcutaneous (SC) injection every 2 weeks through Week 50. Starting at Week 16, nonresponder participants originally randomized to baricitinib continued to receive baricitinib 4 mg administered orally once daily through Week 52. Participants continued to take background MTX therapy throughout study.

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

"Not completed" participants include participants who were rescued during Part A and discontinued study during Part B.

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 administered orally once daily through Week 52 and an adalimumab placebo SC injection every 2 weeks through Week 50.
Starting at Week 16, nonresponder participants originally randomized to baricitinib will continue to receive baricitinib 4 mg administered orally once daily through Week 52.

Investigational medicinal product name	Adalimumab Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Adalimumab placebo administered by SC injection every 2 weeks through Week 50.

Arm title	Adalimumab

Arm description:

Adalimumab 40 mg administered by SC injection every 2 weeks through Week 50 and baricitinib placebo orally once daily through Week 52. Starting at Week 16, participants who are nonresponders will be rescued with baricitinib 4 mg orally once daily through Week 52. Participants will continue to take background MTX therapy throughout study.

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

"Not completed" participants include participants who were rescued during Part A and discontinued study during Part B.

Arm type	Active comparator
Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Adalimumab 40 mg administered by SC injection every 2 weeks through Week 50 and baricitinib placebo orally once daily through Week 52.
Starting at Week 16, participants who are nonresponders will be rescued with baricitinib 4 mg orally once daily through Week 52.

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

Dosage and administration details:

Baricitinib placebo administered orally once daily through Week 52.

Number of subjects in period 1	Placebo	Baricitinib	Adalimumab
Started	488	487	330
Rescued	128 [1]	35 [2]	40 [3]
Completed	424	449	302
Not completed	64	38	28
Adverse event, serious fatal	1	2	-
Physician decision	1	-	-
Consent withdrawn by subject	17	8	15
Adverse event, non-fatal	23	22	9
Sponsor Decision	4	-	-
Lost to follow-up	-	1	-
Entry Criteria Not Met	-	1	1
Lack of efficacy	18	4	3

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	Treatment Period Part B (Weeks 24 to 52)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Placebo administered by SC injection every 2 weeks through Week 50. At Week 24, participants were given baricitinib 4 milligram (mg) orally once daily through Week 52. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily through Week 52. Participants continued to take background methotrexate (MTX) therapy throughout study.

Placebo arm also receives baricitinib during this period.

Arm type	Placebo

Investigational medicinal product name	Adalimumab Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Adalimumab placebo administered by SC injection every 2 weeks through Week 50.

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

Dosage and administration details:

Baricitinib 4 mg administered orally once daily through Week 52 and an adalimumab placebo SC injection every 2 weeks through Week 50.

Arm title	Baricitinib

Arm description:

Baricitinib 4 mg administered orally once daily through Week 52 and an adalimumab placebo SC injection every 2 weeks through Week 50. Starting at Week 16, nonresponder participants originally randomized to baricitinib continued to receive baricitinib 4 mg administered orally once daily through Week 52. Participants continued to take background MTX therapy throughout study.

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

Dosage and administration details:

Baricitinib 4 mg administered orally once daily through Week 52 and an adalimumab placebo SC injection every 2 weeks through Week 50.
Starting at Week 16, nonresponder participants originally randomized to baricitinib continued to receive baricitinib 4 mg administered orally once daily through Week 52.

Investigational medicinal product name	Adalimumab Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Adalimumab placebo administered by SC injection every 2 weeks through Week 50.

Arm title	Adalimumab

Arm description:

Adalimumab 40 mg administered by SC injection every 2 weeks through Week 50 and baricitinib placebo orally once daily through Week 52. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily through Week 52. Participants continued to take background MTX therapy throughout study.

Arm type	Active comparator
Investigational medicinal product name	Adalimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Adalimumab 40 mg administered by SC injection every 2 weeks through Week 50 and baricitinib placebo orally once daily through Week 52.
Starting at Week 16, participants who are nonresponders were rescued with baricitinib 4 mg orally once daily through Week 52.
Participants continued to take background MTX therapy throughout study.

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

Dosage and administration details:

Baricitinib placebo administered orally once daily through Week 52.

Number of subjects in period 2[4]	Placebo	Baricitinib	Adalimumab
Started	310	424	267
Received at Least 1 Dose of Study Drug	306	424	267
Rescued	5 [5]	8 [6]	11 [7]
Completed	293	402	251
Not completed	17	22	16
Adverse event, serious fatal	1	-	1
Consent withdrawn by subject	4	3	7
Physician decision	-	1	-
Adverse event, non-fatal	10	16	6
Sponsor Decision	1	2	-
Lost to follow-up	-	-	1
Lack of efficacy	1	-	1

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: Excludes participants rescued during Part A.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Nonresponders could be rescued at the discretion of the investigator.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Nonresponders could be rescued at the discretion of the investigator.

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Nonresponders could be rescued at the discretion of the investigator.

Period 3

Period 3 title	Follow-up Period
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 - 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 patients who were rescued or switched to Baricitinib 4 mg.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Adalimumab 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

Number of subjects in period 3[8]	Placebo - Follow-up	Baricitinib - Follow-up	Adalimumab Follow-up
Started	33	76	20
Completed	33	76	20

Notes:

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

Baseline characteristics

Reporting groups

Reporting group title	Placebo

Reporting group description:

Placebo administered orally (PO) once daily (QD) through Week 24. At Week 24, participants were given baricitinib 4 milligram (mg) orally once daily through Week 52. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily through Week 52. Participants continued to take background methotrexate (MTX) therapy throughout study.

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

"Not completed" participants include participants who were rescued during Part A and discontinued study during Part B.

Reporting group title	Baricitinib

Reporting group description:

Baricitinib 4 mg administered orally once daily through Week 52 and an adalimumab placebo by subcutaneous (SC) injection every 2 weeks through Week 50. Starting at Week 16, nonresponder participants originally randomized to baricitinib continued to receive baricitinib 4 mg administered orally once daily through Week 52. Participants continued to take background MTX therapy throughout study.

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

"Not completed" participants include participants who were rescued during Part A and discontinued study during Part B.

Reporting group title	Adalimumab

Reporting group description:

Adalimumab 40 mg administered by SC injection every 2 weeks through Week 50 and baricitinib placebo orally once daily through Week 52. Starting at Week 16, participants who are nonresponders will be rescued with baricitinib 4 mg orally once daily through Week 52. Participants will continue to take background MTX therapy throughout study.

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

"Not completed" participants include participants who were rescued during Part A and discontinued study during Part B.

Reporting group values	Placebo	Baricitinib	Adalimumab
Number of subjects	488	487	330
Age categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	53.4	53.5	52.9
standard deviation	± 11.8	± 12.2	± 12.3
Gender, Male/Female Units: participants			
Female	382	375	251
Male	106	112	79
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	26	19	18
Asian	148	143	101
Native Hawaiian or Other Pacific Islander	0	0	0

Black or African American	4	2	4
White	302	312	204
More than one race	7	11	3
Unknown or Not Reported	1	0	0
Region of Enrollment Units: Subjects			
Argentina	91	107	57
Belgium	2	3	3
Canada	5	4	2
China	21	22	11
Croatia	1	0	0
Czech Republic	16	10	10
France	8	8	7
Germany	0	0	2
Greece	1	0	2
Hungary	18	11	8
Japan	93	93	63
Korea, Republic of	21	21	15
Latvia	2	2	5
Lithuania	4	12	10
Mexico	50	36	39
Poland	26	35	19
Portugal	1	1	1
Romania	8	6	2
Russian Federation	27	28	23
Slovakia	8	8	4
Slovenia	4	1	0
South Africa	24	21	11
Spain	15	11	5
Taiwan	6	5	7
United Kingdom	2	6	0
United States	34	36	24
Duration of Rheumatoid Arthritis Units: years			
arithmetic mean	10.4	10.3	9.6
standard deviation	± 8.7	± 8.8	± 8.5
Tender Joint Count of 68 Evaluable Joints Units: Number of Joints			
arithmetic mean	23.3	23.4	23.4
standard deviation	± 13.5	± 13	± 13.7
Swollen Joint Count of 66 Evaluable Joints Units: Number of Joints			
arithmetic mean	15.5	15	15.4
standard deviation	± 9.4	± 8.2	± 9.1
High Sensitivity C-Reactive Protein (hsCRP) Units: milligrams per liter (mg/L)			
arithmetic mean	19.66	22.2	21.78
standard deviation	± 20.97	± 22.85	± 20.83

Reporting group values	Total		
Number of subjects	1305		
Age categorical Units: Subjects			

Age Continuous Units: years arithmetic mean standard deviation	- -		
Gender, Male/Female Units: participants			
Female	1008		
Male	297		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	63		
Asian	392		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	10		
White	818		
More than one race	21		
Unknown or Not Reported	1		
Region of Enrollment Units: Subjects			
Argentina	255		
Belgium	8		
Canada	11		
China	54		
Croatia	1		
Czech Republic	36		
France	23		
Germany	2		
Greece	3		
Hungary	37		
Japan	249		
Korea, Republic of	57		
Latvia	9		
Lithuania	26		
Mexico	125		
Poland	80		
Portugal	3		
Romania	16		
Russian Federation	78		
Slovakia	20		
Slovenia	5		
South Africa	56		
Spain	31		
Taiwan	18		
United Kingdom	8		
United States	94		

Duration of Rheumatoid Arthritis 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: milligrams per liter (mg/L) arithmetic mean standard deviation	- -		

End points

End points reporting groups

Reporting group title	Placebo

Reporting group description:

Placebo administered orally (PO) once daily (QD) through Week 24. At Week 24, participants were given baricitinib 4 milligram (mg) orally once daily through Week 52. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily through Week 52. Participants continued to take background methotrexate (MTX) therapy throughout study.

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

"Not completed" participants include participants who were rescued during Part A and discontinued study during Part B.

Reporting group title	Baricitinib

Reporting group description:

Baricitinib 4 mg administered orally once daily through Week 52 and an adalimumab placebo by subcutaneous (SC) injection every 2 weeks through Week 50. Starting at Week 16, nonresponder participants originally randomized to baricitinib continued to receive baricitinib 4 mg administered orally once daily through Week 52. Participants continued to take background MTX therapy throughout study.

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

"Not completed" participants include participants who were rescued during Part A and discontinued study during Part B.

Reporting group title	Adalimumab

Reporting group description:

Adalimumab 40 mg administered by SC injection every 2 weeks through Week 50 and baricitinib placebo orally once daily through Week 52. Starting at Week 16, participants who are nonresponders will be rescued with baricitinib 4 mg orally once daily through Week 52. Participants will continue to take background MTX therapy throughout study.

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

"Not completed" participants include participants who were rescued during Part A and discontinued study during Part B.

Reporting group title	Placebo

Reporting group description:

Placebo administered by SC injection every 2 weeks through Week 50. At Week 24, participants were given baricitinib 4 milligram (mg) orally once daily through Week 52. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily through Week 52. Participants continued to take background methotrexate (MTX) therapy throughout study.

Placebo arm also receives baricitinib during this period.

Reporting group title	Baricitinib

Reporting group description:

Baricitinib 4 mg administered orally once daily through Week 52 and an adalimumab placebo SC injection every 2 weeks through Week 50. Starting at Week 16, nonresponder participants originally randomized to baricitinib continued to receive baricitinib 4 mg administered orally once daily through Week 52. Participants continued to take background MTX therapy throughout study.

Reporting group title	Adalimumab

Reporting group description:

Adalimumab 40 mg administered by SC injection every 2 weeks through Week 50 and baricitinib placebo orally once daily through Week 52. Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily through Week 52. Participants continued to take background MTX therapy throughout study.

Reporting group title	Placebo - Follow-up

Reporting group description:

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

Reporting group title	Baricitinib - Follow-up

Reporting group description:

No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug. Includes patients who were rescued or switched to Baricitinib 4 mg.

Reporting group title	Adalimumab Follow-up

Reporting group description:

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

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

Subject analysis set description:

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

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

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

End point description:

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

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

End point type	Primary

End point timeframe:

Week 12

End point values	Placebo	Baricitinib	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	488	487	330	
Units: percentage of participants				
number (not applicable)	40.2	69.6	61.2	

Statistical analyses

Statistical analysis title	Statistical Analysis for ACR20
Comparison groups	Baricitinib v Placebo
Number of subjects included in analysis	975
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Regression, Logistic

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

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

End point description:

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

The mTSS at a time point is the sum of the erosion (range from 0 to 280) and JSN (range from 0 to 168) scores, for a maximum score of 448.

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

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Placebo	Baricitinib	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	452	470	312	
Units: units on a scale				
arithmetic mean (standard deviation)	0.84 (± 2.32)	0.35 (± 1.59)	0.29 (± 1.47)	

Statistical analyses

No statistical analyses for this end point

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

End point description:

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

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

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo	Baricitinib	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	488	487	330	
Units: units on a scale				
arithmetic mean (standard deviation)	-0.33 (± 0.51)	-0.65 (± 0.59)	-0.56 (± 0.54)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Disease Activity Score (DAS) modified to include 28 joint count (DAS28) consisted of 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: DAS28-CRP=0.56*square root (sqrt)(TJC28)+0.28*sqrt(SJC28)+0.36*natural log(CRP+1)+0.014*Patient's Global VAS+0.96. Scores ranged 1.0-9.4, where lower scores indicated less disease activity.

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

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Placebo	Baricitinib	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	488	487	330	
Units: units on a scale				
arithmetic mean (standard deviation)	-1.01 (± 1.12)	-2.27 (± 1.22)	-1.98 (± 1.28)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving American College of Rheumatology 50% (ACR50) and 70% (ACR70) Response

End point title	Percentage of Participants Achieving American College of

	Rheumatology 50% (ACR50) and 70% (ACR70) Response

End point description:

ACR50 and ACR70 Responder Index is a composite of clinical, laboratory, and functional measures in RA. ACR50 and ACR70 Responder is a participant who has at least 50% or 70% improvement, respectively, in both tender and swollen joint counts and in at least 3 of the following 5 criteria: Physician's Global Assessment of Disease Activity, Patient's Global Assessment of Disease Activity, HAQ-DI, pain due to arthritis, and hsCRP. Participants with missing responses and participants who discontinued study or drug or were rescued before analysis time point were deemed non-responders.

Analysis Population Description: mITT population: 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, Week 24, Week 52

End point values	Placebo	Baricitinib	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	488[1]	487	330	
Units: percentage of participants				
number (not applicable)				
ACR50 Week 12	16.8	45	34.8	
ACR50 Week 24	19.3	50.5	45.5	
ACR50 Week 52	99999999	55.9	47	
ACR70 Week 12	4.7	18.9	12.7	
ACR70 Week 24	8	29.8	21.8	
ACR70 Week 52	9999999	37.2	30.6	

Notes:

[1] - 9999999: No data available. There is no Placebo Arm at week 52.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point timeframe:

Baseline, Week 12, Week 24, Week 52

End point values	Placebo	Baricitinib	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	481[2]	478	324	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 12	-13.53 (± 13.88)	-23 (± 12.66)	-20.42 (± 13.47)	
Week 24	-14.21 (± 15.13)	-25.04 (± 13.61)	-22.92 (± 14.63)	
Week 52	99999999 (± 99999999)	-26.44 (± 14.42)	-23.48 (± 15.28)	

Notes:

[2] - 9999999= No data available. There is no Placebo Arm at week 52.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point type	Secondary

End point timeframe:

Week 12, Week 24, Week 52

End point values	Placebo	Baricitinib	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	488[3]	478	324	
Units: percentage of participants				
number (not applicable)				
Week 12	1.8	8.4	7.3	
Week 24	3.1	16	13.6	
Week 52	9999999	22.6	17.9	

Notes:

[3] - 9999999: No data available. There is no Placebo Arm at week 52.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point type	Secondary

End point timeframe:

Week 12, Week 24, Week 52

End point values	Placebo	Baricitinib	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	488[4]	487	330	
Units: percentage of participants				
number (not applicable)				
Week 12	1	7.2	5.2	
Week 24	2.7	12.1	10	
Week 52	9999999	15.6	13	

Notes:

[4] - 9999999: No data available. There is no Placebo Arm at week 52.

Statistical analyses

No statistical analyses for this end point

Secondary: Median of Individual Participant Mean Duration of Morning Joint Stiffness in the Prior 7 Days as Collected in Electronic Diaries

End point title	Median of Individual Participant Mean Duration of Morning Joint Stiffness in the Prior 7 Days as Collected in Electronic Diaries

End point description:

Participants recorded the duration of their morning joint stiffness (MJS) in hours and minutes into electronic diaries daily. If morning joint stiffness 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 was calculated. A decrease in duration of morning joint stiffness indicated an improvement in the participant's condition.

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of 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	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	479	479	323	
Units: Minutes				
median (confidence interval 95%)	60 (60 to 75)	27.1 (20 to 30)	36.6 (30 to 45.7)	

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

End point description:

Participants rated the severity of their morning joint stiffness by selecting a number from 0 to 10 that best described their overall level of morning joint stiffness 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 was calculated.

Analysis Population Description: mITT population: 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	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	479	479	323	
Units: units on a scale				
arithmetic mean (standard deviation)	4.1 (± 2.3)	3 (± 2.2)	3.4 (± 2.3)	

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

End point description:

Participants rated their tiredness by selecting a number from 0 to 10 that best described their worst tiredness during the last 24 hours, where 0 represents "no tiredness" and 10 represents "as bad as you can imagine". Participants reported their worst tiredness in electronic diaries. The average value across the 7 days preceding each visit is calculated.

Analysis Population Description: mITT population: 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	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	479	479	323	
Units: units on a scale				
arithmetic mean (standard deviation)	4.4 (± 2.3)	3.6 (± 2.2)	3.9 (± 2.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Worst Joint Pain NRS in the prior 7 days as collected in electronic diaries

End point title	Mean Worst Joint Pain NRS in the prior 7 days as collected in electronic diaries

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 was calculated.

Analysis Population Description: mITT population: 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	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	479	479	323	
Units: units on a scale				
arithmetic mean (standard deviation)	4.6 (± 2.2)	3.4 (± 2.2)	4 (± 2.3)	

Statistical analyses

No statistical analyses for this end point

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

End point title	Change from Baseline in Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-F) scale scores

End point description:

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

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

End point type	Secondary

End point timeframe:

Baseline, Week 12, Week 24, Week 52

End point values	Placebo	Baricitinib	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	475[5]	479	320	
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 12	6.8 (± 9.9)	9.6 (± 10.4)	9.5 (± 10.1)	
Week 24	6.6 (± 10.4)	10.4 (± 10.8)	9.9 (± 11.2)	
Week 52	9999999 (± 9999999)	10.8 (± 10.9)	9.8 (± 10.8)	

Notes:

[5] - 9999999: No data available. There is no Placebo Arm at week 52.

Statistical analyses

No statistical analyses for this end point

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

End point title	Change from baseline in Mental Component Score (MCS),

	Physical Component Score (PCS) of the Medical Outcomes Study 36-Item Short Form Health Survey Version 2 Acute (SF-36v2 Acute)

End point description:

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

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

End point type	Secondary

End point timeframe:

Baseline, Week 12, Week 24, Week 52

End point values	Placebo	Baricitinib	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	475[6]	479	320	
Units: units on a scale				
arithmetic mean (standard deviation)				
MCS Week 12	3.2 (± 10.3)	3.3 (± 10.5)	3.8 (± 10.8)	
MCS Week 24	2.2 (± 11.4)	3.8 (± 10.9)	3.9 (± 11.6)	
MCS Week 52	9999999 (± 9999999)	4 (± 10.8)	3.7 (± 11.2)	
PCS Week 12	4.3 (± 7.1)	8.9 (± 8.1)	7.6 (± 8.2)	
PCS Week 24	4.6 (± 7.8)	9.9 (± 8.2)	8.3 (± 9.1)	
PCS Week 52	9999999 (± 9999999)	10.4 (± 9)	9 (± 9.2)	

Notes:

[6] - 9999999: No data available. There is no Placebo Arm at week 52.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

Analysis Population Description: mITT population: all randomized participants who received at least 1 dose of study drug, with a baseline value and at least 1 post-baseline value. Missing values due to

discontinuation of study or drug, rescue, or missing data were imputed using mLOCF.

End point type	Secondary

End point timeframe:

Baseline, Week 12, Week 24, Week 52

End point values	Placebo	Baricitinib	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	475[7]	479	320	
Units: units on a scale				
arithmetic mean (standard deviation)				
Index Score (US Algorithm) Week 12	0.073 (± 0.151)	0.132 (± 0.156)	0.13 (± 0.159)	
Index Score (US Algorithm) Week 24	0.065 (± 0.168)	0.143 (± 0.168)	0.137 (± 0.167)	
Index Score (US Algorithm) Week 52	9999999 (± 9999999)	0.152 (± 0.163)	0.141 (± 0.189)	
Index Score (UK Algorithm) Week 12	0.107 (± 0.221)	0.188 (± 0.228)	0.186 (± 0.232)	
Index Score (UK Algorithm) Week 24	0.094 (± 0.247)	0.203 (± 0.244)	0.195 (± 0.245)	
Index Score (UK Algorithm) Week 52	9999999 (± 9999999)	0.215 (± 0.235)	0.198 (± 0.273)	

Notes:

[7] - 9999999: No data available. There is no Placebo Arm at week 52.

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point type	Secondary

End point timeframe:

Baseline, Week 12, Week 24, Week 52

End point values	Placebo	Baricitinib	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	458[8]	474	315	
Units: units on a scale				
arithmetic mean (standard deviation)				
Absenteeism Week 12 (n=160,168,118)	0.5 (± 27.7)	-4.9 (± 20.6)	-0.5 (± 25.7)	
Absenteeism Week 24 (n=118,139,102)	-1.6 (± 24.5)	-1.8 (± 25.2)	-3.2 (± 23.8)	
Absenteeism Week 52 (n=NA,124,92)	9999999 (± 9999999)	-3.8 (± 25.1)	-3.7 (± 24.3)	
Presenteeism Week 12 (n=147,160,113)	-11 (± 23)	-21 (± 26)	-16 (± 24)	
Presenteeism Week 24 (n=110,134,99)	-11 (± 22)	-23 (± 27)	-22 (± 26)	
Presenteeism Week 52 (n=NA,119,88)	9999999 (± 9999999)	-25 (± 27)	-25 (± 27)	
Work Productivity Loss Week 12 (n=147,160,113)	-10.4 (± 24.3)	-21.6 (± 28)	-14 (± 25.6)	
Work Productivity Loss Week 24 (n=110,134,99)	-9 (± 24.9)	-22.1 (± 30.2)	-21.4 (± 27.2)	
Work Productivity Loss Week 24 (n=NA,119,88)	9999999 (± 9999999)	-24.4 (± 30.1)	-24.6 (± 29.8)	
Activity Impairment Week 12 (n=458,474,315)	-11 (± 25)	-25 (± 26)	-20 (± 25)	
Activity Impairment Week 24 (n=333,430,272)	-16 (± 26)	-28 (± 27)	-26 (± 26)	
Activity Impairment Week 52 (n=NA,396,240)	99999999 (± 9999999)	-30 (± 27)	-28 (± 27)	

Notes:

[8] - 9999999: No data available. There is no Placebo Arm at week 52.

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in joint space narrowing (JSN) and bone erosion scores

End point title	Change From Baseline in joint space narrowing (JSN) and bone erosion scores

End point description:

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

mITT population: Missing values due to discontinuation of study, rescue, or missing data were imputed using LE.

End point type	Secondary

End point timeframe:

Baseline, up to Week52

End point values	Placebo	Baricitinib	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	452	473	312	
Units: units on a scale				
arithmetic mean (standard deviation)				
Joint Space Narrowing Week 24 (n= 452, 470, 312)	0.27 (± 1.15)	0.1 (± 0.74)	0.09 (± 0.52)	
Joint Space Narrowing Week 52 (n= 452, 473, 312)	0.56 (± 2.33)	0.18 (± 1.02)	0.17 (± 1)	
Bone Erosion Score Week 24 (n=452, 470, 312)	0.57 (± 1.58)	0.25 (± 1.12)	0.2 (± 1.08)	
Bone Erosion Score Week 52 (n= 452, 473, 312)	1.15 (± 3.21)	0.42 (± 1.91)	0.34 (± 2)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

End point type	Secondary

End point timeframe:

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

End point values	Baricitinib			
Subject group type	Subject analysis set			
Number of subjects analysed	635			
Units: nanomole/Liter (nmol/L)				
geometric mean (geometric coefficient of variation)	143 (± 19.7)			

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

End point type	Secondary

End point timeframe:

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

End point values	Baricitinib			
Subject group type	Subject analysis set			
Number of subjects analysed	635			
Units: nanomole*hr/Liter (nmol*hr/L)				
geometric mean (geometric coefficient of variation)	1120 (± 45.8)			

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

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

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

End point type	Secondary

End point timeframe:

Baseline, Week 12, Week 24, Week 52

End point values	Placebo	Baricitinib	Adalimumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	475[9]	479	320	
Units: millimeter				
arithmetic mean (standard deviation)				
Self-Perceived Health Week 12	7.9 (± 26.2)	14.9 (± 25.8)	10.7 (± 26.9)	
Self-Perceived Health Week 24	5.6 (± 27.1)	17.5 (± 28.3)	12.6 (± 28.9)	
Self-Perceived Health Week 52	99999999 (± 99999999)	19.9 (± 28)	13.3 (± 29.7)	

Notes:
[9] - 9999999: No data available. There is no Placebo Arm at week 52.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Follow-up

Adverse event reporting additional description:

I4V-MC-JADV

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.0

Reporting groups

Reporting group title	Placebo Treatment A

Reporting group description:

Placebo administered orally (PO) once daily (QD) through Week 24 and placebo administered by subcutaneous (SC) injection every 2 weeks through Week 50.

At Week 24, participants were given baricitinib 4 milligram (mg) orally once daily through Week 52.

Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily through Week 52.

Participants continued to take background methotrexate (MTX) therapy throughout

Reporting group title	Baricitinib Treatment A

Reporting group description:

Baricitinib 4 mg administered orally once daily through Week 52 and an adalimumab placebo SC injection every 2 weeks through Week 50.

Starting at Week 16, nonresponder participants originally randomized to baricitinib continued to receive baricitinib 4 mg administered orally once daily through Week 52.

Participants continued to take background MTX therapy throughout study.

Reporting group title	Adalimumab Treatment A

Reporting group description:

Adalimumab 40 mg administered by SC injection every 2 weeks through Week 50 and baricitinib placebo orally once daily through Week 52.

Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily through Week 52.

Participants continued to take background MTX therapy throughout study.

Reporting group title	Placebo Treatment B

Reporting group description:

Placebo administered PO QD through Week 24 and placebo administered by SC injection every 2 weeks through Week 50.

At Week 24, participants were given baricitinib 4 mg orally once daily through Week 52.

Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily through Week 52.

Participants continued to take background MTX therapy throughout study.

Reporting group title	Baricitinib Treatment B

Reporting group description:

Baricitinib 4 mg administered orally once daily through Week 52 and an adalimumab placebo SC injection every 2 weeks through Week 50.

Starting at Week 16, nonresponder participants originally randomized to baricitinib continued to receive baricitinib 4 mg administered orally once daily through Week 52.

Participants continued to take background MTX therapy throughout study.

Reporting group title	Adalimumab Treatment B

Reporting group description:

Adalimumab 40 mg administered by SC injection every 2 weeks through Week 50 and baricitinib placebo orally once daily through Week 52.

Starting at Week 16, participants who were nonresponders were rescued with baricitinib 4 mg orally once daily through Week 52.

Participants continued to take background MTX therapy throughout study.

Reporting group title	Rescue

Reporting group description:

Baricitinib 4 mg administered PO QD through Week 52. Participants continued to take background MTX therapy throughout study.

Reporting group title	Placebo - Follow-up

Reporting group description:

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

Reporting group title	Baricitinib - Follow-up

Reporting group description:

No study drug received. Participants return for safety follow-up visit 28 days after the last dose of study drug. Includes participants who were rescued or switched to Baricitinib 4 mg.

Reporting group title	Adalimumab Follow-up

Reporting group description:

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

Serious adverse events	Placebo Treatment A	Baricitinib Treatment A	Adalimumab Treatment A
Total subjects affected by serious adverse events			
subjects affected / exposed	26 / 488 (5.33%)	26 / 487 (5.34%)	7 / 330 (2.12%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (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
clear cell renal cell carcinoma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

lung squamous cell carcinoma stage iii			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (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
lymphoproliferative disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
ovarian cancer			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[1]	1 / 382 (0.26%)	0 / 375 (0.00%)	0 / 251 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
squamous cell carcinoma of lung			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
uterine leiomyoma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[2]	1 / 382 (0.26%)	0 / 375 (0.00%)	0 / 251 (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
Vascular disorders			
circulatory collapse			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
hypotension			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	1 / 330 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
thrombophlebitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (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
Surgical and medical procedures			
bladder repair			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
fracture treatment			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
hysterectomy			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[3]	1 / 382 (0.26%)	0 / 375 (0.00%)	0 / 251 (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
knee arthroplasty			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
non-cardiac chest pain			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
metrorrhagia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[4]	0 / 382 (0.00%)	1 / 375 (0.27%)	0 / 251 (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
Respiratory, thoracic and mediastinal disorders			
acute respiratory failure			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	1 / 330 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
interstitial lung disease			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (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
nasal septum perforation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (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
pleurisy			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia aspiration			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
pneumonitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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 failure			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
confusional state			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
generalised anxiety disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
insomnia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (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
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femoral neck fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (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
fall			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
humerus fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (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
joint injury			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	1 / 330 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
laceration			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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 concussion syndrome			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
radius fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

spinal compression fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ulna fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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 failure			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	1 / 487 (0.21%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (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
sinus bradycardia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (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
supraventricular tachycardia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (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			
cerebrovascular accident			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (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
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	2 / 487 (0.41%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lymphocytosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (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
neutropenia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
cataract			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	1 / 330 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
glaucoma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
macular fibrosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
retinal detachment			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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			
diarrhoea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenal ulcer haemorrhage			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (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
enterocolitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric ulcer			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (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
inguinal hernia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
jejunal ulcer			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
large intestine polyp			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

pancreatitis acute			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (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
Hepatobiliary disorders			
bile duct stone			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 488 (0.41%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholangitis sclerosing			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (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
cholelithiasis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (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
drug-induced liver injury			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
dermatitis allergic			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (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
Renal and urinary disorders			
acute kidney injury			

alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (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
calculus urinary			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	1 / 330 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nephrolithiasis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
nephrosclerosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal impairment			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	1 / 330 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
back pain			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (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
bursitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
chondrocalcinosis pyrophosphate			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (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
intervertebral disc protrusion			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (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
myositis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
osteoarthritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
osteoporosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	1 / 487 (0.21%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

rheumatoid arthritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	4 / 488 (0.82%)	1 / 487 (0.21%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
arthritis bacterial			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
arthritis infective			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	1 / 330 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atypical pneumonia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
bacteraemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (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
cellulitis			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 488 (0.00%)	2 / 487 (0.41%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholecystitis infective			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
cystitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	1 / 330 (0.30%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
epiglottitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (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
escherichia sepsis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 488 (0.41%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

herpes zoster			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	2 / 487 (0.41%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
kidney infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (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
muscle abscess			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (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
necrotising fasciitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	1 / 487 (0.21%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
pneumonia pseudomonal			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis acute			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (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
sepsis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
soft tissue infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
tuberculosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (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 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (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
diabetes mellitus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	1 / 487 (0.21%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
hyponatraemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (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
hypoproteinaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 488 (0.20%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo Treatment B	Baricitinib Treatment B	Adalimumab Treatment B
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 306 (3.92%)	16 / 424 (3.77%)	9 / 267 (3.37%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer			

alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
clear cell renal cell carcinoma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	1 / 424 (0.24%)	0 / 267 (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
lung squamous cell carcinoma stage iii			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
lymphoproliferative disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
ovarian cancer			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[1]	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
squamous cell carcinoma of lung			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
uterine leiomyoma			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed[2]	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
Vascular disorders			
circulatory collapse			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
hypotension			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
thrombophlebitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
Surgical and medical procedures			
bladder repair			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (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
fracture treatment			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (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
hysterectomy			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed[3]	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
knee arthroplasty			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
non-cardiac chest pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
metrorrhagia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[4]	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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 failure			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (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
nasal septum perforation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
pleurisy			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia aspiration			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	1 / 424 (0.24%)	0 / 267 (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
pneumonitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	1 / 424 (0.24%)	0 / 267 (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
respiratory failure			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
confusional state			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (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
generalised anxiety disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	1 / 424 (0.24%)	0 / 267 (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
insomnia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
femoral neck fracture			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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 18.0			
subjects affected / exposed	2 / 306 (0.65%)	0 / 424 (0.00%)	0 / 267 (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
femur fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	1 / 424 (0.24%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
humerus fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
joint injury			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
laceration			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post concussion syndrome			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (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

radius fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (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 compression fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	1 / 424 (0.24%)	0 / 267 (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
spinal fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ulna fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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			
acute myocardial infarction			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	1 / 424 (0.24%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiac failure			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	1 / 424 (0.24%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sinus bradycardia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
supraventricular tachycardia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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			
cerebrovascular accident			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
transient ischaemic attack			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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 18.0			

subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
lymphocytosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
neutropenia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	1 / 424 (0.24%)	0 / 267 (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
Eye disorders			
cataract			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
glaucoma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
macular fibrosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
retinal detachment			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	1 / 424 (0.24%)	0 / 267 (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
duodenal ulcer haemorrhage			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
enterocolitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric ulcer			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (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
inguinal hernia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
jejunal ulcer			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	1 / 424 (0.24%)	0 / 267 (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
large intestine polyp			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
pancreatitis acute			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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			
bile duct stone			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
cholangitis sclerosing			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
cholelithiasis			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
drug-induced liver injury			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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			
dermatitis allergic			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
calculus urinary			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
nephrolithiasis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
nephrosclerosis			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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 impairment			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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			
arthralgia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
back pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
bursitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chondrocalcinosis pyrophosphate			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (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
myositis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (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
osteoarthritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
osteoporosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	1 / 424 (0.24%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rheumatoid arthritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	1 / 424 (0.24%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
arthritis bacterial			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
arthritis infective			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
atypical pneumonia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	1 / 424 (0.24%)	0 / 267 (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
bacteraemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	1 / 424 (0.24%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	1 / 424 (0.24%)	0 / 267 (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
cholecystitis infective			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cystitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

disseminated tuberculosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
epiglottitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
escherichia sepsis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	1 / 267 (0.37%)
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 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
herpes zoster			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (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
kidney infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
muscle abscess			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
necrotising fasciitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	1 / 424 (0.24%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia pseudomonal			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	1 / 267 (0.37%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis acute			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (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
pyelonephritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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

soft tissue infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
tuberculosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
urinary tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	2 / 424 (0.47%)	0 / 267 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
viral infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (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
Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (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
diabetes mellitus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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
hyponatraemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 306 (0.33%)	0 / 424 (0.00%)	0 / 267 (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
hypoproteinaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (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	Rescue	Placebo - Follow-up	Baricitinib - Follow-up
Total subjects affected by serious adverse events			
subjects affected / exposed	17 / 227 (7.49%)	2 / 33 (6.06%)	0 / 76 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
clear cell renal cell carcinoma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lung squamous cell carcinoma stage iii			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
lymphoproliferative disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 227 (0.44%)	0 / 33 (0.00%)	0 / 76 (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
ovarian cancer			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[1]	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
squamous cell carcinoma of lung			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 227 (0.44%)	0 / 33 (0.00%)	0 / 76 (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
uterine leiomyoma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[2]	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
Vascular disorders			
circulatory collapse			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
hypotension			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
thrombophlebitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
Surgical and medical procedures			
bladder repair			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
fracture treatment			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
hysterectomy			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[3]	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
knee arthroplasty			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
non-cardiac chest pain			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	1 / 227 (0.44%)	0 / 33 (0.00%)	0 / 76 (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
Reproductive system and breast disorders			
metrorrhagia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[4]	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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 failure			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
chronic obstructive pulmonary disease			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
nasal septum perforation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
pleurisy			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia aspiration			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
pneumonitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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 failure			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	1 / 33 (3.03%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
confusional state			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
generalised anxiety disorder			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
insomnia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ankle fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
femoral neck fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
femur fracture			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
humerus fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
joint injury			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
laceration			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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 concussion syndrome			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
radius fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

spinal compression fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 227 (0.44%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ulna fracture			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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			
acute myocardial infarction			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 227 (0.44%)	0 / 33 (0.00%)	0 / 76 (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
cardiac failure			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
sinus bradycardia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
supraventricular tachycardia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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			
cerebrovascular accident			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 227 (0.44%)	0 / 33 (0.00%)	0 / 76 (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
transient ischaemic attack			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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 18.0			
subjects affected / exposed	2 / 227 (0.88%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lymphocytosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
neutropenia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
cataract			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
glaucoma			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 227 (0.44%)	0 / 33 (0.00%)	0 / 76 (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
macular fibrosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
retinal detachment			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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			
diarrhoea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
duodenal ulcer haemorrhage			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
enterocolitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 227 (0.88%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastric ulcer			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
inguinal hernia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 227 (0.44%)	0 / 33 (0.00%)	0 / 76 (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
jejunal ulcer			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
large intestine polyp			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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

pancreatitis acute			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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			
bile duct stone			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
cholangitis sclerosing			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
cholelithiasis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 227 (0.44%)	0 / 33 (0.00%)	0 / 76 (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
drug-induced liver injury			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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			
dermatitis allergic			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
acute kidney injury			

alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
calculus urinary			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
nephrolithiasis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 227 (0.44%)	0 / 33 (0.00%)	0 / 76 (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
nephrosclerosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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 impairment			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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			
arthralgia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
back pain			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
bursitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
chondrocalcinosis pyrophosphate			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
osteoarthritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 227 (0.44%)	0 / 33 (0.00%)	0 / 76 (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
osteoporosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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 18.0			
subjects affected / exposed	0 / 227 (0.00%)	1 / 33 (3.03%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
arthritis bacterial			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 227 (0.44%)	0 / 33 (0.00%)	0 / 76 (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
arthritis infective			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
atypical pneumonia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
bacteraemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bronchitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cellulitis			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
cholecystitis infective			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
cystitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
epiglottitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
escherichia sepsis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

herpes zoster			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
kidney infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
muscle abscess			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
necrotising fasciitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pneumonia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	1 / 33 (3.03%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
pneumonia pseudomonal			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis acute			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sepsis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 227 (0.44%)	1 / 33 (3.03%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
soft tissue infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 227 (0.44%)	0 / 33 (0.00%)	0 / 76 (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
tuberculosis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 227 (0.44%)	0 / 33 (0.00%)	0 / 76 (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
urinary tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 227 (0.44%)	0 / 33 (0.00%)	0 / 76 (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
viral infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Metabolism and nutrition disorders			
dehydration			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
diabetes mellitus			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	1 / 227 (0.44%)	0 / 33 (0.00%)	0 / 76 (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
hyponatraemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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
hypoproteinaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (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	Adalimumab Follow-up		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
breast cancer			

alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
clear cell renal cell carcinoma				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
lung squamous cell carcinoma stage iii				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
lymphoproliferative disorder				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ovarian cancer				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed[1]	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
squamous cell carcinoma of lung				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
uterine leiomyoma				
alternative dictionary used: MedDRA 18.0				

subjects affected / exposed[2]	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
circulatory collapse			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
hypotension			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
thrombophlebitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
bladder repair			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
fracture treatment			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
hysterectomy			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed[3]	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
knee arthroplasty				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
non-cardiac chest pain				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
metrorrhagia				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed[4]	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
acute respiratory failure				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
chronic obstructive pulmonary disease				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (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 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
nasal septum perforation				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pleurisy				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonia aspiration				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonitis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
respiratory failure				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
confusional state				
alternative dictionary used: MedDRA 18.0				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
generalised anxiety disorder				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
insomnia				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
alanine aminotransferase increased				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
aspartate aminotransferase increased				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
ankle fracture				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
femoral neck fracture				
alternative dictionary used: MedDRA 18.0				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
fall				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
femur fracture				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
humerus fracture				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
joint injury				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
laceration				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
post concussion syndrome				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

radius fracture				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
road traffic accident				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
spinal compression fracture				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
spinal fracture				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ulna fracture				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
acute myocardial infarction				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cardiac failure				
alternative dictionary used: MedDRA 18.0				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
myocardial infarction				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sinus bradycardia				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
supraventricular tachycardia				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
cerebrovascular accident				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
transient ischaemic attack				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
anaemia				
alternative dictionary used: MedDRA 18.0				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
lymphocytosis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
neutropenia				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
cataract				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
glaucoma				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
macular fibrosis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
retinal detachment				
alternative dictionary used: MedDRA 18.0				

subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
diarrhoea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
duodenal ulcer haemorrhage			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
enterocolitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
gastric ulcer			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
gastrointestinal haemorrhage			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
inguinal hernia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
jejunal ulcer				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
large intestine polyp				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pancreatitis acute				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
bile duct stone				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cholangitis sclerosing				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cholelithiasis				
alternative dictionary used: MedDRA 18.0				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
drug-induced liver injury				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
dermatitis allergic				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
acute kidney injury				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
calculus urinary				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
nephrolithiasis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
nephrosclerosis				
alternative dictionary used: MedDRA 18.0				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
renal impairment				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
arthralgia				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
back pain				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bursitis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
chondrocalcinosis pyrophosphate				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
intervertebral disc protrusion				
alternative dictionary used: MedDRA 18.0				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
myositis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
osteoarthritis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
osteoporosis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
rheumatoid arthritis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
arthritis bacterial				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
arthritis infective				
alternative dictionary used: MedDRA 18.0				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
atypical pneumonia				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bacteraemia				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
bronchitis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cellulitis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cholecystitis infective				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cystitis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

disseminated tuberculosis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
epiglottitis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
escherichia sepsis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastroenteritis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
herpes zoster				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
kidney infection				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
muscle abscess				
alternative dictionary used: MedDRA 18.0				

subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
necrotising fasciitis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonia				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonia pseudomonal				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pyelonephritis acute				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pyelonephritis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sepsis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

soft tissue infection				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tuberculosis				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
urinary tract infection				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
viral infection				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
dehydration				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
diabetes mellitus				
alternative dictionary used: MedDRA 18.0				
subjects affected / exposed	0 / 20 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
diabetes mellitus inadequate control				
alternative dictionary used: MedDRA 18.0				

subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
hyponatraemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
hypoproteinaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Notes:

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

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

Non-serious adverse events	Placebo Treatment A	Baricitinib Treatment A	Adalimumab Treatment A
Total subjects affected by non-serious adverse events			
subjects affected / exposed	177 / 488 (36.27%)	196 / 487 (40.25%)	132 / 330 (40.00%)
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	5 / 488 (1.02%)	8 / 487 (1.64%)	9 / 330 (2.73%)
occurrences (all)	5	9	9
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	3 / 488 (0.61%)	13 / 487 (2.67%)	2 / 330 (0.61%)
occurrences (all)	3	15	2
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	13 / 488 (2.66%)	9 / 487 (1.85%)	11 / 330 (3.33%)
occurrences (all)	13	9	11
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	12 / 488 (2.46%)	14 / 487 (2.87%)	13 / 330 (3.94%)
occurrences (all)	12	17	16
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	15 / 488 (3.07%)	16 / 487 (3.29%)	4 / 330 (1.21%)
occurrences (all)	16	16	4
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[5]	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences (all)	0	0	0
calculus prostatic			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[6]	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences (all)	0	0	0
erectile dysfunction			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[7]	0 / 106 (0.00%)	0 / 112 (0.00%)	2 / 79 (2.53%)
occurrences (all)	0	0	2
ovarian cyst			

alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[8]	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
constipation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 488 (0.00%)	0 / 487 (0.00%)	0 / 330 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	14 / 488 (2.87%)	11 / 487 (2.26%)	8 / 330 (2.42%)
occurrences (all)	16	12	10
dyspepsia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	7 / 488 (1.43%)	9 / 487 (1.85%)	8 / 330 (2.42%)
occurrences (all)	7	9	8
nausea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	6 / 488 (1.23%)	14 / 487 (2.87%)	9 / 330 (2.73%)
occurrences (all)	7	15	9
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	8 / 488 (1.64%)	7 / 487 (1.44%)	7 / 330 (2.12%)
occurrences (all)	9	7	7
Skin and subcutaneous tissue disorders			
rash			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	5 / 488 (1.02%)	3 / 487 (0.62%)	7 / 330 (2.12%)
occurrences (all)	6	3	7
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	8 / 488 (1.64%)	9 / 487 (1.85%)	10 / 330 (3.03%)
occurrences (all)	8	9	13
rheumatoid arthritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	14 / 488 (2.87%)	5 / 487 (1.03%)	4 / 330 (1.21%)
occurrences (all)	15	6	5
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	14 / 488 (2.87%)	19 / 487 (3.90%)	8 / 330 (2.42%)
occurrences (all)	14	22	8
nasopharyngitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	35 / 488 (7.17%)	37 / 487 (7.60%)	34 / 330 (10.30%)
occurrences (all)	39	41	40
influenza			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	4 / 488 (0.82%)	12 / 487 (2.46%)	5 / 330 (1.52%)
occurrences (all)	5	12	5
pharyngitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	14 / 488 (2.87%)	12 / 487 (2.46%)	12 / 330 (3.64%)
occurrences (all)	14	13	12
upper respiratory tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	14 / 488 (2.87%)	15 / 487 (3.08%)	13 / 330 (3.94%)
occurrences (all)	15	17	16
urinary tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	16 / 488 (3.28%)	21 / 487 (4.31%)	13 / 330 (3.94%)
occurrences (all)	16	25	14
Metabolism and nutrition disorders			
hypercholesterolaemia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	7 / 488 (1.43%)	15 / 487 (3.08%)	2 / 330 (0.61%)
occurrences (all)	7	15	2
hyperlipidaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 488 (0.41%)	10 / 487 (2.05%)	3 / 330 (0.91%)
occurrences (all)	2	11	3

Non-serious adverse events	Placebo Treatment B	Baricitinib Treatment B	Adalimumab Treatment B
Total subjects affected by non-serious adverse events			
subjects affected / exposed	58 / 306 (18.95%)	70 / 424 (16.51%)	38 / 267 (14.23%)
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

blepharitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[5]	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
calculus prostatic			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[6]	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
erectile dysfunction			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[7]	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[8]	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
constipation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
nausea			

alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
rash			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	7 / 306 (2.29%)	9 / 424 (2.12%)	4 / 267 (1.50%)
occurrences (all)	7	9	4
rheumatoid arthritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	11 / 306 (3.59%)	12 / 424 (2.83%)	5 / 267 (1.87%)
occurrences (all)	12	12	5
nasopharyngitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	15 / 306 (4.90%)	24 / 424 (5.66%)	14 / 267 (5.24%)
occurrences (all)	19	26	15
influenza			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	3 / 306 (0.98%)	10 / 424 (2.36%)	1 / 267 (0.37%)
occurrences (all)	3	10	1
pharyngitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	10 / 306 (3.27%)	4 / 424 (0.94%)	7 / 267 (2.62%)
occurrences (all)	12	4	7
upper respiratory tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	10 / 306 (3.27%)	13 / 424 (3.07%)	4 / 267 (1.50%)
occurrences (all)	10	13	4
urinary tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	5 / 306 (1.63%)	10 / 424 (2.36%)	5 / 267 (1.87%)
occurrences (all)	5	10	6
Metabolism and nutrition disorders			
hypercholesterolaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 306 (0.00%)	0 / 424 (0.00%)	0 / 267 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Rescue	Placebo - Follow-up	Baricitinib - Follow-up
Total subjects affected by non-serious adverse events			
subjects affected / exposed	46 / 227 (20.26%)	3 / 33 (9.09%)	0 / 76 (0.00%)
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	5 / 227 (2.20%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	5	0	0
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	8 / 227 (3.52%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	9	0	0
Eye disorders			
blepharitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	1 / 33 (3.03%)	0 / 76 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[5]	1 / 47 (2.13%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
calculus prostatic			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[6]	1 / 47 (2.13%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	1	0	0
erectile dysfunction			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[7]	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
ovarian cyst			

alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[8]	0 / 227 (0.00%)	0 / 26 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
constipation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	5 / 227 (2.20%)	1 / 33 (3.03%)	0 / 76 (0.00%)
occurrences (all)	6	1	0
diarrhoea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
rash			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
rheumatoid arthritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	6 / 227 (2.64%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	7	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	9 / 227 (3.96%)	2 / 33 (6.06%)	0 / 76 (0.00%)
occurrences (all)	11	2	0
influenza			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	5 / 227 (2.20%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	5	0	0
pharyngitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	5 / 227 (2.20%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	10	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	6 / 227 (2.64%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	7	0	0
urinary tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	5 / 227 (2.20%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	6	0	0
Metabolism and nutrition disorders			
hypercholesterolaemia			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 227 (0.00%)	0 / 33 (0.00%)	0 / 76 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Adalimumab Follow-up		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 20 (15.00%)		
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Vascular disorders			
hypertension			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
headache			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Eye disorders			

blepharitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[5]	0 / 20 (0.00%)		
occurrences (all)	0		
calculus prostatic			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[6]	0 / 20 (0.00%)		
occurrences (all)	0		
erectile dysfunction			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[7]	0 / 20 (0.00%)		
occurrences (all)	0		
ovarian cyst			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed[8]	1 / 16 (6.25%)		
occurrences (all)	1		
Gastrointestinal disorders			
constipation			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
diarrhoea			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
dyspepsia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
nausea			

alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
cough			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
rash			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
rheumatoid arthritis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
nasopharyngitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
influenza			
alternative dictionary used: MedDRA 18.0			

subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
pharyngitis			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
upper respiratory tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
urinary tract infection			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
hypercholesterolaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		
hyperlipidaemia			
alternative dictionary used: MedDRA 18.0			
subjects affected / exposed	0 / 20 (0.00%)		
occurrences (all)	0		

Notes:

[5] - 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.
[6] - 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.
[7] - 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.
[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported