Clinical trial results:
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of LY2127399 in Patients with Moderate to Severe Rheumatoid Arthritis (RA) who had an Inadequate Response to Methotrexate Therapy (FLEX M)

Summary

EudraCT number	2010-022205-17
Trial protocol	HU LT BG PL
Global end of trial date	21 January 2014

Results information

Result version number	v1 (current)
This version publication date	11 April 2018
First version publication date	11 April 2018

Trial information

Trial identification

Sponsor protocol code	H9B-MC-BCDM

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01198002
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 11352

Notes:

Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center , Indianapolis, IN, United States, 46285
Public contact	Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-CTLilly,
Scientific contact	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	21 January 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	21 January 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary purpose of this study is to help answer if LY2127399 is safe and effective in the treatment of rheumatoid arthritis while on a background treatment of methotrexate.
This study is comprised of 3 periods:

Period 1: 52-week blinded treatment

Period 2: additional 48-week unblinded treatment

Period 3: 48-week post-treatment follow-up

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	02 December 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 167
Country: Number of subjects enrolled	Taiwan: 31
Country: Number of subjects enrolled	Slovakia: 11
Country: Number of subjects enrolled	Ukraine: 68
Country: Number of subjects enrolled	Lithuania: 20
Country: Number of subjects enrolled	Russian Federation: 72
Country: Number of subjects enrolled	Colombia: 51
Country: Number of subjects enrolled	Sri Lanka: 5
Country: Number of subjects enrolled	India: 14
Country: Number of subjects enrolled	Hungary: 25
Country: Number of subjects enrolled	Mexico: 64
Country: Number of subjects enrolled	Argentina: 50
Country: Number of subjects enrolled	Malaysia: 8
Country: Number of subjects enrolled	Brazil: 41

Country: Number of subjects enrolled	Poland: 100
Country: Number of subjects enrolled	Croatia: 2
Country: Number of subjects enrolled	Romania: 4
Country: Number of subjects enrolled	South Africa: 48
Country: Number of subjects enrolled	Bulgaria: 32
Country: Number of subjects enrolled	Japan: 158
Country: Number of subjects enrolled	New Zealand: 2
Country: Number of subjects enrolled	Korea, Republic of: 68
Worldwide total number of subjects	1041
EEA total number of subjects	194

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)	900
From 65 to 84 years	141
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Study had a blinded Treatment Period 1 (Weeks 0-52), a non-blinded Treatment Period 2 (Weeks 52-100) and a post-treatment follow-up (24-48 weeks in length). All participants were assessed for nonresponse at Week 16 with non-responders (NR) defined as participants with <20% improvement from baseline in both tender and swollen joint counts.

Period 1

Period 1 title	Treatment Period 1 (Weeks 0-52)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	120 mg LY2127399

Arm description:

Treatment Period 1 (Weeks 0-52): A loading dose of 240 milligrams (mg) (2 injections of 120 mg) of LY2127399, followed by maintenance dosing of 120 mg of LY2127399 administered subcutaneously (SC) every 4 weeks (Q4W). For blinding purposes, participants alternated injections of LY2127399 and injections of placebo every 2 weeks (Q2W).
At Week 16, responders received 1 injection of 120 mg of LY2127399 and 1 injection of placebo, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 1.
Treatment Period 2 (Weeks 52-100): At Week 52, Week 16 responders received 1 injection of 120 mg of LY2127399 and 1 injection of placebo, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 2.
At Week 16, NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 100-week treatment period.

Arm type	Experimental
Investigational medicinal product name	120 mg LY2127399
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Treatment Period 1 (Weeks 0-52): A loading dose of 240 milligrams (mg) (2 injections of 120 mg) of LY2127399, followed by maintenance dosing of 120 mg of LY2127399 administered subcutaneously (SC) every 4 weeks (Q4W). For blinding purposes, participants alternated injections of LY2127399 and injections of placebo every 2 weeks (Q2W).

At Week 16, responders received 1 injection of 120 mg of LY2127399 and 1 injection of placebo, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 1.

Treatment Period 2 (Weeks 52-100): At Week 52, Week 16 responders received 1 injection of 120 mg of LY2127399 and 1 injection of placebo, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 2.

At Week 16, NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 100-week treatment period.

Arm title	90 mg LY2127399

Arm description:

Treatment Period 1 (Weeks 0-52): A loading dose of 180 mg of LY2127399 (2 injections of 90 mg), followed by maintenance dosing of 90 mg of LY2127399 administered SC Q2W.

At Week 16, responders received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 1.
Treatment Period 2 (Weeks 52-100): At Week 52, Week 16 responders received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 2.
At Week 16, NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 100-week treatment period.

Arm type	Experimental
Investigational medicinal product name	90 mg LY2127399
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Treatment Period 1 (Weeks 0-52): A loading dose of 180 mg of LY2127399 (2 injections of 90 mg), followed by maintenance dosing of 90 mg of LY2127399 administered SC Q2W.

At Week 16, responders received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 1.

Treatment Period 2 (Weeks 52-100): At Week 52, Week 16 responders received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 2.

Arm title	Placebo

Arm description:

Treatment Period 1 (Weeks 0-52): A loading dose of 2 injections of placebo, followed by maintenance dosing of 1 injection of placebo administered SC Q2W.
At Week 16, responders received 2 injections of placebo, followed by 1 injection of placebo Q2W for the rest of the Treatment Period 1.
Treatment Period 2 (Weeks 52-100): At Week 52, responders were randomized to receive either 2 injections of 120 mg of LY2127399, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 2 or 2 injections of 90 mg of LY2127399, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 2.
At Week 16, NR received a loading dose of 180 mg of LY2127399 (2 injections of 90 mg), followed by 90 mg of LY2127399 Q2W for the rest of the 100-week treatment period.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Treatment Period 1 (Weeks 0-52): A loading dose of 2 injections of placebo, followed by maintenance dosing of 1 injection of placebo administered SC Q2W.

At Week 16, responders received 2 injections of placebo, followed by 1 injection of placebo Q2W for the rest of the Treatment Period 1.

Treatment Period 2 (Weeks 52-100): At Week 52, responders were randomized to receive either 2 injections of 120 mg of LY2127399, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 2 or 2 injections of 90 mg of LY2127399, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 2.

Number of subjects in period 1	120 mg LY2127399	90 mg LY2127399	Placebo
Started	345	347	349
Received at Least 1 Dose of Study Drug	345	345	348
Week 16 NR	58 [1]	62 [2]	90
Post-Treatment Follow-Up Population	293	303	307
Completed	70	73	80
Not completed	275	274	269
Adverse event, serious fatal	2	-	1
Consent withdrawn by subject	16	21	12
Physician decision	1	2	2
Adverse event, non-fatal	18	11	11
Sponsor Decision	213	216	224
Lost to follow-up	-	2	-
Entry Criteria Not Met	1	3	3
Lack of efficacy	10	9	6
Protocol deviation	14	10	10

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: All participants were assessed for nonresponse at Week 16 with non-responders (NR) defined as participants with <20% improvement from baseline in both tender and swollen joint counts.
[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: All participants were assessed for nonresponse at Week 16 with non-responders (NR) defined as participants with <20% improvement from baseline in both tender and swollen joint counts.

Period 2

Period 2 title	Treatment Period 2 (Weeks 52-100)
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	120 mg LY2127399

Arm description:

Treatment Period 1 (Weeks 0-52): A loading dose of 240 milligrams (mg) (2 injections of 120 mg) of LY2127399, followed by maintenance dosing of 120 mg of LY2127399 administered subcutaneously (SC) every 4 weeks (Q4W). For blinding purposes, participants alternated injections of LY2127399 and injections of placebo every 2 weeks (Q2W).
At Week 16, responders received 1 injection of 120 mg of LY2127399 and 1 injection of placebo, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 1.
Treatment Period 2 (Weeks 52-100): At Week 52, Week 16 responders received 1 injection of 120 mg of LY2127399 and 1 injection of placebo, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 2.
At Week 16, NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 100-week treatment period.

Arm type	Experimental

Investigational medicinal product name	120 mg LY2127399
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Treatment Period 1 (Weeks 0-52): A loading dose of 240 milligrams (mg) (2 injections of 120 mg) of LY2127399, followed by maintenance dosing of 120 mg of LY2127399 administered subcutaneously (SC) every 4 weeks (Q4W). For blinding purposes, participants alternated injections of LY2127399 and injections of placebo every 2 weeks (Q2W).

At Week 16, responders received 1 injection of 120 mg of LY2127399 and 1 injection of placebo, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 1.

Treatment Period 2 (Weeks 52-100): At Week 52, Week 16 responders received 1 injection of 120 mg of LY2127399 and 1 injection of placebo, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 2.

At Week 16, NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 100-week treatment period.

Arm title	90 mg LY2127399

Arm description:

Treatment Period 1 (Weeks 0-52): A loading dose of 180 mg of LY2127399 (2 injections of 90 mg), followed by maintenance dosing of 90 mg of LY2127399 administered SC Q2W.
At Week 16, responders received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 1.
Treatment Period 2 (Weeks 52-100): At Week 52, Week 16 responders received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 2.
At Week 16, NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 100-week treatment period.

Arm type	Experimental
Investigational medicinal product name	90 mg LY2127399
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Treatment Period 1 (Weeks 0-52): A loading dose of 180 mg of LY2127399 (2 injections of 90 mg), followed by maintenance dosing of 90 mg of LY2127399 administered SC Q2W.

At Week 16, responders received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 1.

Treatment Period 2 (Weeks 52-100): At Week 52, Week 16 responders received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 2.

Arm title	Placebo

Arm description:

Treatment Period 1 (Weeks 0-52): A loading dose of 2 injections of placebo, followed by maintenance dosing of 1 injection of placebo administered SC Q2W.
At Week 16, responders received 2 injections of placebo, followed by 1 injection of placebo Q2W for the rest of the Treatment Period 1.
Treatment Period 2 (Weeks 52-100): At Week 52, responders were randomized to receive either 2 injections of 120 mg of LY2127399, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 2 or 2 injections of 90 mg of LY2127399, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 2.
At Week 16, NR received a loading dose of 180 mg of LY2127399 (2 injections of 90 mg), followed by 90 mg of LY2127399 Q2W for the rest of the 100-week treatment period.

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Treatment Period 1 (Weeks 0-52): A loading dose of 2 injections of placebo, followed by maintenance dosing of 1 injection of placebo administered SC Q2W.

At Week 16, responders received 2 injections of placebo, followed by 1 injection of placebo Q2W for the rest of the Treatment Period 1.

Treatment Period 2 (Weeks 52-100): At Week 52, responders were randomized to receive either 2 injections of 120 mg of LY2127399, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 2 or 2 injections of 90 mg of LY2127399, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 2.

Number of subjects in period 2	120 mg LY2127399	90 mg LY2127399	Placebo
Started	70	73	80
Completed	1	0	2
Not completed	69	73	78
Physician decision	1	-	1
Adverse event, non-fatal	2	-	1
Sponsor Decision	62	70	75
Lost to follow-up	-	2	-
Entry Criteria Not Met	1	-	-
Lack of efficacy	3	1	1

Baseline characteristics

Reporting groups	
Reporting group title	120 mg LY2127399

Reporting group description:

Treatment Period 1 (Weeks 0-52): A loading dose of 240 milligrams (mg) (2 injections of 120 mg) of LY2127399, followed by maintenance dosing of 120 mg of LY2127399 administered subcutaneously (SC) every 4 weeks (Q4W). For blinding purposes, participants alternated injections of LY2127399 and injections of placebo every 2 weeks (Q2W).
At Week 16, responders received 1 injection of 120 mg of LY2127399 and 1 injection of placebo, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 1.
Treatment Period 2 (Weeks 52-100): At Week 52, Week 16 responders received 1 injection of 120 mg of LY2127399 and 1 injection of placebo, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 2.
At Week 16, NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 100-week treatment period.

Reporting group title	90 mg LY2127399

Reporting group description:

Treatment Period 1 (Weeks 0-52): A loading dose of 180 mg of LY2127399 (2 injections of 90 mg), followed by maintenance dosing of 90 mg of LY2127399 administered SC Q2W.
At Week 16, responders received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 1.
Treatment Period 2 (Weeks 52-100): At Week 52, Week 16 responders received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 2.
At Week 16, NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 100-week treatment period.

Reporting group title	Placebo

Reporting group description:

Treatment Period 1 (Weeks 0-52): A loading dose of 2 injections of placebo, followed by maintenance dosing of 1 injection of placebo administered SC Q2W.
At Week 16, responders received 2 injections of placebo, followed by 1 injection of placebo Q2W for the rest of the Treatment Period 1.
Treatment Period 2 (Weeks 52-100): At Week 52, responders were randomized to receive either 2 injections of 120 mg of LY2127399, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 2 or 2 injections of 90 mg of LY2127399, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 2.
At Week 16, NR received a loading dose of 180 mg of LY2127399 (2 injections of 90 mg), followed by 90 mg of LY2127399 Q2W for the rest of the 100-week treatment period.

Reporting group values	120 mg LY2127399	90 mg LY2127399	Placebo
Number of subjects	345	347	349
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	290	311	299
From 65-84 years	55	36	50
85 years and over	0	0	0

Gender, Male/Female Units:			
Male	51	56	57
Female	294	291	292
Race Units: Subjects			
American Indian or Alaska Native	20	18	15
Asian	100	102	101
Native Hawaiian or Other Pacific Islander	0	1	0
Black or African American	22	19	22
White	191	197	200
More than once Race	9	7	7
Unknown or Not Reported	3	3	4
Ethnicity Units: Subjects			
Hispanic or Latino	63	67	61
Not Hispanic or Latino	140	131	140
Unknown or Not Reported	142	149	148

Reporting group values	Total		
Number of subjects	1041		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	900		
From 65-84 years	141		
85 years and over	0		
Gender, Male/Female Units:			
Male	164		
Female	877		
Race Units: Subjects			
American Indian or Alaska Native	53		
Asian	303		
Native Hawaiian or Other Pacific Islander	1		
Black or African American	63		
White	588		
More than once Race	23		
Unknown or Not Reported	10		
Ethnicity Units: Subjects			
Hispanic or Latino	191		
Not Hispanic or Latino	411		

Unknown or Not Reported	439		

End points

End points reporting groups

Reporting group title	120 mg LY2127399

Reporting group description:

Treatment Period 1 (Weeks 0-52): A loading dose of 240 milligrams (mg) (2 injections of 120 mg) of LY2127399, followed by maintenance dosing of 120 mg of LY2127399 administered subcutaneously (SC) every 4 weeks (Q4W). For blinding purposes, participants alternated injections of LY2127399 and injections of placebo every 2 weeks (Q2W).
At Week 16, responders received 1 injection of 120 mg of LY2127399 and 1 injection of placebo, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 1.
Treatment Period 2 (Weeks 52-100): At Week 52, Week 16 responders received 1 injection of 120 mg of LY2127399 and 1 injection of placebo, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 2.
At Week 16, NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 100-week treatment period.

Reporting group title	90 mg LY2127399

Reporting group description:

Treatment Period 1 (Weeks 0-52): A loading dose of 180 mg of LY2127399 (2 injections of 90 mg), followed by maintenance dosing of 90 mg of LY2127399 administered SC Q2W.
At Week 16, responders received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 1.
Treatment Period 2 (Weeks 52-100): At Week 52, Week 16 responders received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 2.
At Week 16, NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 100-week treatment period.

Reporting group title	Placebo

Reporting group description:

Treatment Period 1 (Weeks 0-52): A loading dose of 2 injections of placebo, followed by maintenance dosing of 1 injection of placebo administered SC Q2W.
At Week 16, responders received 2 injections of placebo, followed by 1 injection of placebo Q2W for the rest of the Treatment Period 1.
Treatment Period 2 (Weeks 52-100): At Week 52, responders were randomized to receive either 2 injections of 120 mg of LY2127399, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 2 or 2 injections of 90 mg of LY2127399, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 2.
At Week 16, NR received a loading dose of 180 mg of LY2127399 (2 injections of 90 mg), followed by 90 mg of LY2127399 Q2W for the rest of the 100-week treatment period.

Reporting group title	120 mg LY2127399

Reporting group description:

Treatment Period 1 (Weeks 0-52): A loading dose of 240 milligrams (mg) (2 injections of 120 mg) of LY2127399, followed by maintenance dosing of 120 mg of LY2127399 administered subcutaneously (SC) every 4 weeks (Q4W). For blinding purposes, participants alternated injections of LY2127399 and injections of placebo every 2 weeks (Q2W).
At Week 16, responders received 1 injection of 120 mg of LY2127399 and 1 injection of placebo, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 1.
Treatment Period 2 (Weeks 52-100): At Week 52, Week 16 responders received 1 injection of 120 mg of LY2127399 and 1 injection of placebo, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 2.
At Week 16, NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 100-week treatment period.

Reporting group title	90 mg LY2127399

Reporting group description:

Treatment Period 1 (Weeks 0-52): A loading dose of 180 mg of LY2127399 (2 injections of 90 mg), followed by maintenance dosing of 90 mg of LY2127399 administered SC Q2W.
At Week 16, responders received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 1.
Treatment Period 2 (Weeks 52-100): At Week 52, Week 16 responders received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 2.
At Week 16, NR received 1 injection of 90 mg of LY2127399 and 1 injection of placebo, followed by 90 mg of LY2127399 Q2W for the rest of the 100-week treatment period.

Reporting group title	Placebo

Reporting group description:

Treatment Period 1 (Weeks 0-52): A loading dose of 2 injections of placebo, followed by maintenance dosing of 1 injection of placebo administered SC Q2W.
At Week 16, responders received 2 injections of placebo, followed by 1 injection of placebo Q2W for the rest of the Treatment Period 1.
Treatment Period 2 (Weeks 52-100): At Week 52, responders were randomized to receive either 2 injections of 120 mg of LY2127399, followed by 120 mg of LY2127399 Q4W for the rest of the Treatment Period 2 or 2 injections of 90 mg of LY2127399, followed by 90 mg of LY2127399 Q2W for the rest of the Treatment Period 2.
At Week 16, NR received a loading dose of 180 mg of LY2127399 (2 injections of 90 mg), followed by 90 mg of LY2127399 Q2W for the rest of the 100-week treatment period.

Subject analysis set title	PK subset
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Population PK subset of all participants who received LY2127399.

Primary: Percentage of participants with American College of Rheumatology 20% response (ACR20) at Week 24

End point title	Percentage of participants with American College of Rheumatology 20% response (ACR20) at Week 24

End point description:

ACR Responder Index: Composite of clinical, laboratory, and functional measures of rheumatoid arthritis (RA). ACR20 Responder: had ≥20% improvement from baseline in both 68 tender and 66 swollen joint counts and ≥20% improvement in at least 3 of 5 criteria: participant's and physician's global assessment of disease activity, Health Assessment Questionnaire-Disability Index (HAQ-DI) (which measured participants' perceived degree of difficulty performing daily activities), joint pain, and C-reactive protein (CRP). Percentage of participants achieving ACR20 response=(number of ACR20 responders) / (number of participants treated) * 100. All NR at Week 16 as well as all participants who discontinued study treatment at any time for any reason were defined as NR starting at that time-point and going forward, including Week 24 endpoint.
All randomized participants with evaluable ACR20 responder data.

End point type	Primary

End point timeframe:

Baseline through 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	330[1]	332[2]	335[3]	
Units: percentage of participants				
number (not applicable)	29.7	32.8	25.1	

Notes:

[1] - All randomized participants with evaluable ACR20 responder data.

[2] - All randomized participants with evaluable ACR20 responder data.

[3] - All randomized participants with evaluable ACR20 responder data.

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	120 mg LY2127399 v 90 mg LY2127399 v Placebo

Number of subjects included in analysis	997
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	> 0.05
Method	t-test, 2-sided

Primary: Change from baseline to Week 52 in van der Heijde modified Total Sharp Score (mTSS)

End point title	Change from baseline to Week 52 in van der Heijde modified Total Sharp Score (mTSS)

End point description:

The mTSS quantifies the extent of bone erosions and joint space narrowing for 44 and 42 joints. X-rays of the hands/wrists and feet are scored for erosions on a scale from 0 (no damage) to 5 (complete collapse) and joint space narrowing on a scale from 0 (no damage) to 4 (ankylosis or complete dislocation). Erosions scores (range = 0 to 220 for 44 joints) and narrowing scores (range = 0 to 168 for 42 joints) were added to obtain the mTSS (range = 0 [normal] to 388 [maximal disease]). Least Squares (LS) means were calculated using analysis of covariance (ANCOVA) with treatment and region as fixed factors and baseline as a covariate.

End point type	Primary

End point timeframe:

Baseline, 52 Weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	295[4]	304[5]	306[6]	
Units: units on a scale				
least squares mean (standard error)	1.43 (± 0.27)	0.84 (± 0.27)	1.57 (± 0.27)	

Notes:

[4] - All randomized participants with evaluable mTSS data.

[5] - All randomized participants with evaluable mTSS data.

[6] - All randomized participants with evaluable mTSS data.

Statistical analyses

Statistical analysis title	Statistical Analysis 3
Comparison groups	120 mg LY2127399 v 90 mg LY2127399 v Placebo
Number of subjects included in analysis	905
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	> 0.05
Method	t-test, 2-sided

Primary: Change from baseline to Week 24 in Health Assessment Questionnaire-Disability Index (HAQ-DI)

End point title	Change from baseline to Week 24 in Health Assessment Questionnaire-Disability Index (HAQ-DI)

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 HAQ-DI scores, which ranged from 0 (no disability) to 3 (severe disability). A decrease in HAQ-DI score indicated an improvement in the participant's condition. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Primary

End point timeframe:

Baseline, 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	329[7]	329[8]	328[9]	
Units: units on a scale				
least squares mean (standard error)	-0.26 (± 0.03)	-0.30 (± 0.03)	-0.20 (± 0.03)	

Notes:

[7] - All randomized participants with evaluable HAQ-DI data.

[8] - All randomized participants with evaluable HAQ-DI data.

[9] - All randomized participants with evaluable HAQ-DI data.

Statistical analyses

Statistical analysis title	Stats analysis 2
Comparison groups	120 mg LY2127399 v 90 mg LY2127399 v Placebo
Number of subjects included in analysis	986
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	> 0.05
Method	t-test, 2-sided

Secondary: Percentage of participants with American College of Rheumatology 50% (ACR50) and 70% (ACR70) response

End point title	Percentage of participants with American College of Rheumatology 50% (ACR50) and 70% (ACR70) response

End point description:

ACR Responder Index: Composite of clinical, laboratory, and functional measures of RA. ACR50 Responder: had ≥50% improvement from baseline in both 68 tender joint (TJ) and 66 swollen joint (SJ) counts and ≥50% improvement in at least 3 of 5 criteria: participant's (Pt's) and physician's global assessment of disease activity, HAQ-DI (measured Pts' perceived degree of difficulty performing daily activities), joint pain, and CRP. Percentage of Pt achieving ACR50 response=(number (No.) of ACR50 responders) / (No. of Pts treated) * 100. ACR70 Responder: had ≥70% improvement from baseline in both TJ and SJ counts and ≥70% improvement in at least 3 of same 5 criteria for ACR50. Percentage of Pts achieving ACR70 response= (No. of ACR70 responders) / (No. of Pts treated) * 100. All NR at Week 16 as well as all Pts who discontinued study treatment at any time for any reason were defined as NR starting at that time-point and going forward, including Weeks 24 and 52 endpoints.

End point type	Secondary

End point timeframe:

Baseline through 24 weeks and 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	330[10]	332[11]	335[12]	
Units: percentage of participants				
number (not applicable)				
ACR50- Week 24	10.6	11.1	10.1	
ACR50- Week52	4.2	3.0	4.8	
ACR70- Week 24	3.9	3.0	1.8	
ACR70- Week 52	1.5	1.2	1.8	

Notes:

[10] - All randomized participants with evaluable ACR50 or ACR70 responder data.

[11] - All randomized participants with evaluable ACR50 or ACR70 responder data.

[12] - All randomized participants with evaluable ACR50 or ACR70 responder data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Disease Activity Score based on 28 joint count and C-Reactive Protein Level (DAS28-CRP)

End point title	Change from baseline in Disease Activity Score based on 28 joint count and C-Reactive Protein Level (DAS28-CRP)

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), CRP [milligrams per liter (mg/L)], and participant's global assessment of disease activity using visual analog scale (VAS) (participant global VAS). DAS28-CRP=0.56*square root (sqrt)(TJC28)+0.28*sqrt(SJC28)+0.36*natural log(CRP+1)+0.014*participant global VAS+0.96. Scores ranged from 1.0-9.4, where lower scores indicated less disease activity and remission is DAS28-CRP <2.6. A decrease in DAS28-CRP indicated an improvement in participant's condition. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, 24 weeks and 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	328[13]	327[14]	328[15]	
Units: units on a scale				
least squares mean (standard error)				
Week 24	-1.02 (± 0.07)	-1.00 (± 0.07)	-0.78 (± 0.07)	
Week 52	-1.07 (± 0.07)	-1.00 (± 0.07)	-0.80 (± 0.07)	

Notes:

[13] - All randomized participants with evaluable DAS28-CRP data

[14] - All randomized participants with evaluable DAS28-CRP data

[15] - All randomized participants with evaluable DAS28-CRP data

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with DAS28-CRP Based European League Against Rheumatism (EULAR) response

End point title	Percentage of participants with DAS28-CRP Based European League Against Rheumatism (EULAR) response

End point description:

EULAR Responder index based on 28 joint counts categorizes clinical response based on improvement since baseline in DAS28-CRP. DAS28-CRP scores range from 1.0-9.4, where lower scores indicated less disease activity. High disease activity: DAS28-CRP >5.1, low disease activity: DAS28-CRP <3.2, and remission: DAS28-CRP <2.6. Participants are categorized as EULAR responders or NR based on improvement of DAS28-CRP scores from baseline. EULAR DAS28-CRP responder index defines a good (absolute: <3.2 or >1.2 improvement from baseline), moderate (absolute: 3.2-5.1 or 0.6-1.2 improvement from baseline), or no response (absolute: >5.1 or <0.6 improvement from baseline). Percentage of participants with DAS28-CRP based EULAR response =(number of participants with specific response) / (number of participants analyzed in the group) * 100.

End point type	Secondary

End point timeframe:

Baseline through 24 weeks and 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	328[16]	327[17]	328[18]	
Units: percentage of participants				
number (not applicable)				
Week 24- Good	17.7	16.2	14.3	
Week 24 - Moderate	41.5	38.5	30.8	
Week 24 - No Response	40.9	45.3	54.9	
Week 52 - Good	18.6	14.7	15.9	
Week 52 - Moderate	37.5	39.1	29.0	
Week 52 - No Response	43.9	46.2	55.2	

Notes:

[16] - All randomized participants with evaluable EULAR response data

[17] - All randomized participants with evaluable EULAR response data

[18] - All randomized participants with evaluable EULAR response data

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Medical Outcomes Study 36-Item Short Form (SF-36) Health Survey domain scores and summary scores

End point title	Change from baseline in Medical Outcomes Study 36-Item

	Short Form (SF-36) Health Survey domain scores and summary scores

End point description:

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, 2 component scores (CS), physical CS (PCS) and mental CS (MCS). Domain scores were calculated by summing each item for each domain and transforming scores into a 0-100 scale. Higher scores indicated better health status. If < 50% of the questions within a domain were answered, raw scores were not calculated. PCS score consisted of physical functioning, bodily pain, role-physical, and general health scales. MCS score consisted of social functioning, vitality, mental health, and role-emotional scales. Both PCS and MCS range from 0-100. Higher score indicated better mental or physical health. LS means were calculated using ANCOVA with treatment, region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, 24 weeks and 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	320[19]	322[20]	323[21]	
Units: units on a scale				
least squares mean (standard error)				
Physical functioning - Week 24 (n=320, 322, 323)	2.70 (± 0.48)	3.16 (± 0.47)	2.06 (± 0.47)	
Physical functioning - Week 52 (n=320, 322, 323)	2.15 (± 0.50)	3.22 (± 0.49)	1.82 (± 0.49)	
Bodily pain - Week 24 (n=319, 322, 323)	4.07 (± 0.46)	4.08 (± 0.45)	2.52 (± 0.45)	
Bodily pain - Week 52 (n=319, 322, 323)	3.77 (± 0.47)	4.48 (± 0.46)	2.32 (± 0.46)	
RL - physical problems - Week 24 (n=320, 322, 323)	2.77 (± 0.46)	3.64 (± 0.46)	1.99 (± 0.45)	
RL - physical problems - Week 52 (n=320, 322, 323)	3.01 (± 0.47)	3.79 (± 0.46)	1.82 (± 0.46)	
RL - emotional problems- Week 24 (n=319, 322, 323)	3.20 (± 0.60)	4.81 (± 0.59)	2.91 (± 0.59)	
RL - emotional problems- Week 52 (n=319, 322, 323)	2.84 (± 0.61)	4.34 (± 0.59)	2.56 (± 0.59)	
GH Perception - Week 24 (n=319, 322, 323)	2.60 (± 0.41)	3.72 (± 0.40)	2.54 (± 0.40)	
GH Perception - Week 52 (n=319, 322, 323)	2.89 (± 0.42)	3.41 (± 0.41)	2.18 (± 0.41)	
Mental Health - Week 24 (n=319, 322, 323)	3.39 (± 0.53)	4.47 (± 0.53)	3.28 (± 0.52)	
Mental Health - Week 52 (n=319, 322, 323)	3.01 (± 0.55)	4.37 (± 0.54)	3.10 (± 0.54)	
Social function - Week 24 (n=319, 322, 323)	3.25 (± 0.53)	4.18 (± 0.52)	2.79 (± 0.52)	
Social function - Week 52 (n=319, 322, 323)	3.04 (± 0.53)	3.99 (± 0.52)	2.87 (± 0.52)	
Vitality - Week 24 (n=319, 322, 323)	3.43 (± 0.50)	4.41 (± 0.49)	2.99 (± 0.48)	
Vitality - Week 52 (n=319, 322, 323)	3.10 (± 0.51)	3.96 (± 0.50)	3.02 (± 0.49)	
PCS - Week 24 (n=319, 322, 323)	2.80 (± 0.43)	3.08 (± 0.43)	1.76 (± 0.42)	
PCS - Week 52 (n=319, 322, 323)	2.79 (± 0.44)	3.30 (± 0.43)	1.55 (± 0.43)	
MCS - Week 24 (n=319, 322, 323)	3.34 (± 0.56)	4.74 (± 0.55)	3.33 (± 0.55)	
MCS - Week 52 (n=319, 322, 323)	2.98 (± 0.57)	4.27 (± 0.56)	3.22 (± 0.56)	

Notes:

[19] - All randomized participants with evaluable SF-36 domain and summary scores.

[20] - All randomized participants with evaluable SF-36 domain and summary scores.

[21] - All randomized participants with evaluable SF-36 domain and summary scores.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Brief Fatigue Inventory (BFI) individual items and impact score

End point title	Change from baseline in Brief Fatigue Inventory (BFI) individual items and impact score

End point description:

The BFI is a brief participant-reported questionnaire for the rapid assessment of fatigue severity and the impact of fatigue on daily functioning in the past 24 hours. The BFI contains 10 items; however, Item 1 is not included in the scoring of the scale as it asks about usual fatigue over the past week with the participant answering 'yes' or 'no'. The remaining 9 items assess fatigue severity (3 items) and impact of fatigue on daily functioning (6 items) using an 11-point numeric scale, with 0=no fatigue and 10=fatigue as bad as you can imagine. The fatigue impact subscale score is the average of the non-missing responses to 6 items: general activity, mood, walking ability, normal work, relations with other people, and enjoyment of life. If more than 3 items within the fatigue impact subscale were not answered by a participant, the subscale is set to missing. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, 24 weeks and 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	320[22]	322[23]	323[24]	
Units: units on a scale				
least squares mean (standard error)				
Fatigue-Now - Week 24 (n=320, 322, 323)	-0.86 (± 0.14)	-1.12 (± 0.13)	-0.61 (± 0.13)	
Fatigue-Now - Week 52 (n=320, 322, 323)	-0.79 (± 0.14)	-1.01 (± 0.13)	-0.56 (± 0.13)	
Fatigue-Usual - Week 24 (n=320, 322, 323)	-0.93 (± 0.13)	-1.06 (± 0.13)	-0.61 (± 0.13)	
Fatigue-Usual - Week 52 (n=320, 322, 323)	-0.91 (± 0.14)	-0.97 (± 0.13)	-0.66 (± 0.13)	
Fatigue-Worst - Week 24 (n=320, 322, 323)	-0.98 (± 0.14)	-1.22 (± 0.14)	-0.71 (± 0.14)	
Fatigue-Worst - Week 52 (n=320, 322, 323)	-1.22 (± 0.15)	-1.19 (± 0.14)	-0.81 (± 0.14)	
General Activity - Week 24 (n=320, 322, 323)	-0.93 (± 0.14)	-1.09 (± 0.13)	-0.61 (± 0.13)	
General Activity - Week 52 (n=320, 322, 323	-1.03 (± 0.14)	-1.07 (± 0.13)	-0.61 (± 0.13)	
Mood - Week 24 (n=320, 322, 323)	-0.67 (± 0.14)	-1.01 (± 0.14)	-0.47 (± 0.14)	
Mood - Week 52 (n=320, 322, 323)	-0.86 (± 0.14)	-0.82 (± 0.14)	-0.53 (± 0.14)	

Walking Ability - Week 24 (n=320, 322, 323)	-0.92 (± 0.15)	-1.02 (± 0.14)	-0.44 (± 0.14)	
Walking Ability - Week 52 (n=320, 322, 323)	-0.88 (± 0.14)	-0.98 (± 0.14)	-0.45 (± 0.14)	
Normal Work - Week 24 (n=320, 322, 322)	-0.78 (± 0.14)	-1.07 (± 0.14)	-0.48 (± 0.14)	
Normal Work - Week 52 (n=320, 322, 323)	-0.88 (± 0.14)	-1.00 (± 0.14)	-0.52 (± 0.14)	
Relations with Other - Week 24 (n=320, 322, 322)	-0.39 (± 0.14)	-0.64 (± 0.14)	-0.13 (± 0.14)	
Relations with Other - Week 52 (n=320, 322, 323)	-0.47 (± 0.14)	-0.46 (± 0.14)	-0.16 (± 0.14)	
Enjoyment of Life - Week 24 (n=320, 322, 322)	-0.58 (± 0.15)	-0.82 (± 0.15)	-0.36 (± 0.14)	
Enjoyment of Life - Week 52 (n=320, 322, 323)	-0.66 (± 0.15)	-0.74 (± 0.14)	-0.46 (± 0.14)	
Fatigue Impact Subscale- Week 24(n=320, 322, 323)	-0.71 (± 0.13)	-0.93 (± 0.13)	-0.42 (± 0.23)	
Fatigue Impact Subscale- Week 52 (n=320, 322, 323)	-0.80 (± 0.13)	-0.83 (± 0.13)	-0.46 (± 0.13)	

Notes:

[22] - All randomized participants with evaluable BFI data.

[23] - All randomized participants with evaluable BFI data.

[24] - All randomized participants with evaluable BFI data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in duration of morning stiffness (minutes)

End point title	Change from baseline in duration of morning stiffness (minutes)

End point description:

The Investigator asks participants about the duration of their morning stiffness (in minutes) in and around the joints and records the duration. The Investigator should ask the participants about duration of morning stiffness on the day prior to the study visit to capture actual symptoms. If morning stiffness duration is longer than 12 hours (720 minutes), it was truncated to 720 minutes for statistical presentations and analyses. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, 24 weeks and 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	307[25]	319[26]	314[27]	
Units: minutes				
least squares mean (standard error)				
Week 24 (n=306, 318, 313)	-41.2 (± 5.0)	-32.0 (± 4.8)	-34.5 (± 4.9)	
Week 52 (n= 307, 319, 314)	-41.4 (± 5.2)	-31.2 (± 5.0)	-37.3 (± 5.1)	

Notes:

[25] - All randomized participants with evaluable morning stiffness data.

[26] - All randomized participants with evaluable morning stiffness data.

[27] - All randomized participants with evaluable morning stiffness data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Brief Pain Inventory Short Form (BPI-SF) individual items and interference scores

End point title	Change from baseline in Brief Pain Inventory Short Form (BPI-SF) individual items and interference scores

End point description:

The BPI-SF is a self-reported scale that measures the severity of pain based on the worst pain, least pain, average pain experienced during the past 24-hours and pain based on the pain right now with scores ranging from 0 (no pain) to 10 (pain as severe as you can imagine). Pain interference score is the average of the responses in past 24-hours to 7 items: general activity, mood, walking ability, normal work, relations with other people, sleep, and enjoyment of life [each item scored from 0 (does not interfere) to 10 (completely interferes)]. If more than 3 items of the Pain Interference Score are not answered by a participant, the score were set to missing. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, 24 weeks and 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	320[28]	322[29]	323[30]	
Units: units on a scale				
least squares mean (standard error)				
Pain- Worst- Week 24	-1.1 (± 0.1)	-1.1 (± 0.1)	-0.7 (± 0.1)	
Pain-Worst- Week 52	-1.1 (± 0.1)	-1.3 (± 0.1)	-0.8 (± 0.1)	
Pain-Least- Week 24	-0.3 (± 0.1)	-0.6 (± 0.1)	-0.1 (± 0.1)	
Pain-Least - Week 52	-0.3 (± 0.1)	-0.6 (± 0.1)	-0.1 (± 0.1)	
Pain-Average - Week 24	-0.8 (± 0.1)	-0.9 (± 0.1)	-0.3 (± 0.1)	
Pain-Average - Week 52	-0.7 (± 0.1)	-1.0 (± 0.1)	-0.3 (± 0.1)	
Pain-Now - Week 24	-1.1 (± 0.1)	-1.2 (± 0.1)	-0.5 (± 0.1)	
Pain-Now - Week 52	-1.0 (± 0.1)	-1.3 (± 0.1)	-0.5 (± 0.1)	
General Activity - Week 24	-1.0 (± 0.1)	-1.0 (± 0.1)	-0.6 (± 0.1)	
General Activity - Week 52	-1.0 (± 0.1)	-1.3 (± 0.1)	-0.8 (± 0.1)	
Mood - Week 24	-0.9 (± 0.1)	-1.0 (± 0.1)	-0.6 (± 0.1)	
Mood - Week 52	-1.0 (± 0.1)	-1.1 (± 0.1)	-0.7 (± 0.1)	
Walking Ability - Week 24	-0.9 (± 0.1)	-1.2 (± 0.1)	-0.5 (± 0.1)	
Walking Ability - Week 52	-0.8 (± 0.1)	-1.1 (± 0.1)	-0.6 (± 0.1)	
Relations with Other - Week 24	-0.5 (± 0.1)	-0.6 (± 0.1)	-0.6 (± 0.1)	
Relations with Other - Week 52	-0.5 (± 0.1)	-0.5 (± 0.1)	-0.3 (± 0.1)	
Sleep - Week 24	-1.0 (± 0.1)	-1.1 (± 0.1)	-0.4 (± 0.1)	
Sleep - Week 52	-0.9 (± 0.1)	-0.6 (± 0.1)	-0.5 (± 0.1)	

Enjoyment of Life - Week 24	-0.8 (± 0.1)	-1.2 (± 0.1)	-0.5 (± 0.1)	
Enjoyment of Life - Week 52	-0.9 (± 0.1)	-1.1 (± 0.1)	-0.5 (± 0.1)	
Pain Interference Score - Week 24	-0.89 (± 0.12)	-1.02 (± 0.12)	-0.50 (± 0.12)	
Pain Interference Score - Week 52	-0.85 (± 0.12)	-1.00 (± 0.12)	-0.58 (± 0.12)	

Notes:

[28] - All randomized participants with evaluable BPI-SF scores.

[29] - All randomized participants with evaluable BPI-SF scores.

[30] - All randomized participants with evaluable BPI-SF scores.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with Major Clinical Response (MCR) during 52 weeks

End point title	Percentage of participants with Major Clinical Response (MCR) during 52 weeks

End point description:

Zero participants were analyzed due to early termination of the study and statistical analysis plan (SAP) amendment.

End point type	Secondary

End point timeframe:

Baseline through 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[31]	0[32]	0[33]	
Units: Participants				
number (not applicable)				

Notes:

[31] - Zero participants were analyzed.

[32] - Zero participants were analyzed.

[33] - Zero participants were analyzed.

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with change from baseline in mTSS less than or equal to (≤) 0

End point title	Percentage of participants with change from baseline in mTSS less than or equal to (≤) 0

End point description:

The mTSS quantifies the extent of bone erosions and joint space narrowing for 44 and 42 joints. X-rays of the hands/wrists and feet are scored for erosions on a scale from 0 (no damage) to 5 (complete collapse) and joint space narrowing on a scale from 0 (no damage) to 4 (ankylosis or complete dislocation). Erosions scores (range=0 to 220 for 44 joints) and narrowing scores (range=0 to 168 for 42 joints) were added to obtain the mTSS (range = 0 [normal] to 388 [maximal disease]). Percentage of participants = (number of participants with mTSS ≤0 at Week 24) / (total number of participants analyzed in the group) * 100.

End point type	Secondary

End point timeframe:

Baseline through 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	295[34]	304[35]	306[36]	
Units: percentage of participants				
number (not applicable)	61.0	61.8	56.2	

Notes:

[34] - All randomized participants with evaluable mTSS data.

[35] - All randomized participants with evaluable mTSS data.

[36] - All randomized participants with evaluable mTSS data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to week 52 in B cell subset counts

End point title	Change from baseline to week 52 in B cell subset counts

End point description:

B cell subset counts are: cluster designation (CD)19+ B cell counts, Immature/transitional [CD19+immunoglobulin D (IgD)-CD27-], Mature naïve (CD19+IgD+CD27-), Non-switched memory (CD19+IgD+CD27+) and Memory (CD19+IgD-CD27+). A positive or negative change indicated an increase or decrease, respectively in B cell count. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	326[37]	333[38]	339[39]	
Units: cells/microliter (cells/µL)				
least squares mean (standard error)				
CD19+ (n=326, 333, 339)	-57.1 (± 4.9)	-60.9 (± 4.9)	0.7 (± 4.8)	
CD19+IgD-CD27- (n=321, 330, 336)	-3.1 (± 0.7)	-3.9 (± 0.07)	0.2 (± 0.7)	
CD19+IgD+CD27- (n=321, 330, 336)	-89.4 (± 3.3)	-92.4 (± 3.3)	-3.5 (± 3.2)	
CD19+IgD+CD27+ (n=321, 330, 336)	9.5 (± 1.0)	8.9 (± 1.0)	1.0 (± 1.0)	
CD19+IgD-CD27+ (n=321, 330, 336)	19.7 (± 1.9)	20.6 (± 1.8)	3.2 (± 1.8)	

Notes:

[37] - All randomized participants with evaluable B cell subset counts data

[38] - All randomized participants with evaluable B cell subset counts data

[39] - All randomized participants with evaluable B cell subset counts data

Statistical analyses

No statistical analyses for this end point

Secondary: Population Pharmacokinetics (PK): Constant Clearance

End point title	Population Pharmacokinetics (PK): Constant Clearance

End point description:

Population estimate of constant clearance as determined by population PK analysis. A 2-compartment model was used in PK modeling. Constant clearance is the PK parameter which describes the linear elimination of LY2127399 from serum.

End point type	Secondary

End point timeframe:

Baseline through 52 weeks

End point values	PK subset			
Subject group type	Subject analysis set			
Number of subjects analysed	825[40]			
Units: milliliter per hour (mL/h)				
arithmetic mean (confidence interval 95%)	3.60 (3.46 to 3.73)			

Notes:

[40] - All randomized participants who received at least 1 dose LY2127399 with evaluable PK data

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants developing anti-LY2127399 antibodies

End point title	Percentage of participants developing anti-LY2127399 antibodies

End point description:

Participants with treatment-emergent anti-drug antibodies (ADA) were participants who had any sample from baseline up to and through Week 24 that was a 4-fold increase (2-dilution increase) in immunogenicity titer over baseline titer, or participants who tested negative at baseline and positive post-baseline (at titer of ≥1:20). Percentage of participants with ADA=(number of participants with treatment-emergent ADA) / (number of participants assessed) * 100.

End point type	Secondary

End point timeframe:

Baseline through 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	344[41]	344[42]	347[43]	
Units: percentage of participants				
number (not applicable)	3.8	1.5	4.9	

Notes:

[41] - All randomized participants who received 1 dose of study drug evaluable ADA baseline & postbaseline

[42] - All randomized participants who received 1 dose of study drug evaluable ADA baseline & postbaseline
[43] - All randomized participants who received 1 dose of study drug evaluable ADA baseline & postbaseline

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with No structural progression at Week 52

End point title	Percentage of participants with No structural progression at Week 52

End point description:

No structural progression is defined as the change in mTSS from baseline ≤0. The mTSS quantifies the extent of bone erosions and joint space narrowing for 44 and 42 joints. X-rays of the hands/wrists and feet are scored for erosions on a scale from 0 (no damage) to 5 (complete collapse) and joint space narrowing on a scale from 0 (no damage) to 4 (ankylosis or complete dislocation). Erosions scores (range=0 to 220 for 44 joints) and narrowing scores (range=0 to 168 for 42 joints) were added to obtain the mTSS (range=0 [normal] to 388 [maximal disease]). Percentage of participants=(number of participants with mTSS ≤0 at Week 52) / (total number of participants analyzed in the group) * 100.

End point type	Secondary

End point timeframe:

Baseline through 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	295[44]	304[45]	306[46]	
Units: percentage of participants				
number (not applicable)	55.6	57.6	53.9	

Notes:

[44] - All randomized participants with evaluable mTSS data.

[45] - All randomized participants with evaluable mTSS data.

[46] - All randomized participants with evaluable mTSS data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to Week 24 in mTSS

End point title	Change from baseline to Week 24 in mTSS

End point description:

The mTSS quantifies the extent of bone erosions and joint space narrowing for 44 and 42 joints. X-rays of the hands/wrists and feet are scored for erosions on a scale from 0 (no damage) to 5 (complete collapse) and joint space narrowing on a scale from 0 (no damage) to 4 (ankylosis or complete dislocation). Erosions scores (range=0 to 220 for 44 joints) and narrowing scores (range=0 to 168 for 42 joints) were added to obtain the mTSS (range=0 [normal] to 388 [maximal disease]). LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, 24 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	295[47]	304[48]	306[49]	
Units: units on a scale				
least squares mean (standard error)	0.63 (± 0.14)	0.45 (± 0.14)	0.82 (± 0.14)	

Notes:

[47] - All randomized participants with evaluable mTSS data.

[48] - All randomized participants with evaluable mTSS data.

[49] - All randomized participants with evaluable mTSS data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in serum immunoglobulin (Ig) levels

End point title	Change from baseline in serum immunoglobulin (Ig) levels

End point description:

Immunoglobulins (Ig), or antibodies, are large proteins used by the immune system to identify and neutralize foreign particles such as bacteria and viruses. Their normal blood levels indicate proper immune status. Change from baseline serum immunoglobulin G (IgG), immunoglobulin A (IgA), and immunoglobulin M (IgM) levels are reported. A negative change indicated a decrease in Ig levels. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	342[50]	342[51]	347[52]	
Units: grams/liter (g/L)				
least squares mean (standard error)				
IgA	-0.380 (± 0.028)	-0.382 (± 0.028)	-0.009 (± 0.028)	
IgG	-1.375 (± 0.096)	-1.235 (± 0.097)	-0.176 (± 0.096)	
IgM	-0.235 (± 0.016)	-0.274 (± 0.016)	-0.032 (± 0.016)	

Notes:

[50] - All randomized participants with evaluable serum Ig data.

[51] - All randomized participants with evaluable serum Ig data.

[52] - All randomized participants with evaluable serum Ig data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in joint space narrowing score and bone erosions score (components of mTSS)

End point title	Change from baseline in joint space narrowing score and bone erosions score (components of mTSS)

End point description:

The mTSS quantifies the extent of bone erosions and joint space narrowing for 44 and 42 joints. X-rays of the hands/wrists and feet are scored for erosions on a scale from 0 (no damage) to 5 (complete collapse) and joint space narrowing on a scale from 0 (no damage) to 4 (ankylosis or complete dislocation). Erosions scores (range=0 to 220 for 44 joints) and narrowing scores (range=0 to 168 for 42 joints) were added to obtain the mTSS (range=0 [normal] to 388 [maximal disease]). LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, 24 weeks and 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	295[53]	304[54]	306[55]	
Units: units on a scale				
least squares mean (standard error)				
Joint Space Narrowing - Week 24	0.22 (± 0.09)	0.19 (± 0.09)	0.34 (± 0.09)	
Joint Space Narrowing - Week 52	0.56 (± 0.16)	0.35 (± 0.16)	0.61 (± 0.16)	
Bone Erosions - Week 24	0.40 (± 0.09)	0.26 (± 0.08)	0.48 (± 0.08)	
Bone Erosions - Week 52	0.86 (± 0.17)	0.49 (± 0.17)	0.96 (± 0.17)	

Notes:

[53] - All randomized participants with evaluable mTSS data.

[54] - All randomized participants with evaluable mTSS data.

[55] - All randomized participants with evaluable mTSS data.

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology Percent Improvement (ACR-N)

End point title	American College of Rheumatology Percent Improvement (ACR-N)

End point description:

ACR-N is a continuous measure of clinical, laboratory, and functional outcomes in RA that characterizes percentage (%) of improvement in disease activity from baseline based on ACR core set. This index was calculated as minimum of either a) % change in TJ count, b) % change in SJ count, or c) the median % change of remaining 5 ACR core criteria: If ≥3 components of the 5 ACR core criteria were missing, then c) was set to missing; if any of 3 components a), b), or c) were missing, then ACR-N was set to missing. Percentage of improvement was truncated to range of -100 to 100 to minimize impact of outliers (greater values indicate greater % improvement) and negative scores indicate a decline. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline DAS28-CRP as a covariate.

End point type	Secondary

End point timeframe:

Baseline through 24 weeks and 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	329[56]	326[57]	327[58]	
Units: percentage of improvement				
least squares mean (standard error)				
Week 24	2.0 (± 2.5)	2.1 (± 2.5)	-6.9 (± 2.5)	
Week 52	2.9 (± 2.5)	0.3 (± 2.5)	-7.3 (± 2.5)	

Notes:

[56] - All randomized participants with evaluable ACR-N data.

[57] - All randomized participants with evaluable ACR-N data.

[58] - All randomized participants with evaluable ACR-N data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Tender Joint Count (68 joint count)

End point title	Change from baseline in Tender Joint Count (68 joint count)

End point description:

Tender joint count is the number of tender and painful joints determined for each participant by examination of 68 joints. Joints were assessed by pressure and joint manipulation on physical examination. Participants were asked for pain sensations on these manipulations and watched for spontaneous pain reactions. Any positive response on pressure, movement, or both was translated into a single tender-versus-nontender dichotomy. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, 24 weeks and 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	329[59]	329[60]	334[61]	
Units: joint counts				
least squares mean (standard error)				
Week 24	-7.41 (± 0.72)	-7.88 (± 0.72)	-6.40 (± 0.72)	
Week 52	-7.88 (± 0.73)	-8.09 (± 0.73)	-5.72 (± 0.73)	

Notes:

[59] - All randomized participants with evaluable tender joint count data.

[60] - All randomized participants with evaluable tender joint count data.

[61] - All randomized participants with evaluable tender joint count data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Swollen Joint Count (66 joint count)

End point title	Change from baseline in Swollen Joint Count (66 joint count)

End point description:

Swollen joint count is the number of swollen joints determined for each participant by examination of 66 joints. Joints were classified as either swollen or not swollen. Swelling was defined as palpable

fluctuating synovitis of the joint. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, 24 weeks and 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	329[62]	329[63]	334[64]	
Units: joint counts				
least squares mean (standard error)				
Week 24	-5.38 (± 0.49)	-5.64 (± 0.49)	-4.61 (± 0.49)	
Week 52	-6.10 (± 0.49)	-5.53 (± 0.49)	-4.67 (± 0.49)	

Notes:

[62] - All randomized participants with evaluable swollen joint count data.

[63] - All randomized participants with evaluable swollen joint count data.

[64] - All randomized participants with evaluable swollen joint count data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Participant's Assessment of Pain [Visual Analog Scale (VAS)]

End point title	Change from baseline in Participant's Assessment of Pain [Visual Analog Scale (VAS)]

End point description:

Participant's assessment of their current arthritis pain using VAS ranged from 0 millimeters (mm) (no pain) to 100 mm (worst possible pain). A decrease in pain score indicated an improvement in the participant's condition. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, 24 weeks and 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	329[65]	327[66]	328[67]	
Units: mm				
least squares mean (standard error)				
Week 24	-13.2 (± 1.2)	-14.6 (± 1.2)	-9.0 (± 1.2)	
Week 52	-13.6 (± 1.2)	-14.6 (± 1.2)	-8.7 (± 1.2)	

Notes:

[65] - All randomized participants with evaluable participant's assessment of pain data.

[66] - All randomized participants with evaluable participant's assessment of pain data.

[67] - All randomized participants with evaluable participant's assessment of pain data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Participant's Global Assessment of Disease Activity (VAS)

End point title	Change from baseline in Participant's Global Assessment of Disease Activity (VAS)

End point description:

Participant's assessment of their current arthritis disease activity using VAS ranged from 0 mm (no arthritis activity) to 100 mm (extremely active arthritis). A decrease in disease activity score indicated an improvement in the participant's condition. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, 24 weeks and 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	329[68]	327[69]	328[70]	
Units: mm				
least squares mean (standard error)				
Week 24	-13.6 (± 1.2)	-14.6 (± 1.2)	-9.0 (± 1.2)	
Week 52	-13.2 (± 1.2)	-14.6 (± 1.2)	-8.7 (± 1.2)	

Notes:

[68] - All randomized participants with evaluable participant's assessment of pain data.

[69] - All randomized participants with evaluable participant's assessment of pain data.

[70] - All randomized participants with evaluable participant's assessment of pain data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in Physician's Global Assessment of Disease Activity (VAS)

End point title	Change from baseline in Physician's Global Assessment of Disease Activity (VAS)

End point description:

Physician's assessment of the participant's current arthritis disease activity using VAS ranged from 0 mm (no arthritis activity) to 100 mm (extremely active arthritis). A decrease in disease activity score indicated an improvement in the participant's condition. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, 24 weeks and 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	321[71]	315[72]	314[73]	
Units: mm				
least squares mean (standard error)				
Week 24	-20.7 (± 1.3)	-22.0 (± 1.3)	-17.2 (± 1.3)	
Week 52	-20.4 (± 1.3)	-20.6 (± 1.3)	-17.8 (± 1.3)	

Notes:

[71] - All randomized participants with evaluable physician's global assessment of disease activity data.

[72] - All randomized participants with evaluable physician's global assessment of disease activity data.

[73] - All randomized participants with evaluable physician's global assessment of disease activity data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to Week 52 in HAQ-DI

End point title	Change from baseline to Week 52 in HAQ-DI

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 HAQ-DI scores, which ranged from 0 (no disability) to 3 (severe disability). A decrease in HAQ-DI score indicated an improvement in the participant's condition. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	329[74]	327[75]	328[76]	
Units: units on a scale				
least squares mean (standard error)	-0.24 (± 0.03)	-0.30 (± 0.03)	-0.18 (± 0.03)	

Notes:

[74] - All randomized participants with evaluable HAQ-DI data.

[75] - All randomized participants with evaluable HAQ-DI data.

[76] - All randomized participants with evaluable HAQ-DI data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline to week 52 in absolute B cell counts

End point title	Change from baseline to week 52 in absolute B cell counts

End point description:

Cell-surface marker cluster designation (CD) 3 negative, CD20 positive (CD3-CD20+) defines total mature B cells. B-lymphocyte antigen CD20 is an activated-glycosylated phosphoprotein expressed on the surface of all mature B cells. A positive or negative change indicated an increase or decrease,

respectively in B cell count. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	343[77]	344[78]	348[79]	
Units: cells/microliter (cells/µL)				
least squares mean (standard error)	-56.5 (± 4.5)	-58.6 (± 4.5)	-6.8 (± 4.5)	

Notes:

[77] - All randomized participants with evaluable B cell subset counts data.

[78] - All randomized participants with evaluable B cell subset counts data

[79] - All randomized participants with evaluable B cell subset counts data

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants with ACR20 at Week 52

End point title	Percentage of participants with ACR20 at Week 52

End point description:

ACR Responder Index: Composite of clinical, laboratory, and functional measures of rheumatoid arthritis (RA). ACR20 Responder: had ≥20% improvement from baseline in both 68 tender and 66 swollen joint counts and ≥20% improvement in at least 3 of 5 criteria: participant's and physician's global assessment of disease activity, HAQ-DI (which measured participants' perceived degree of difficulty performing daily activities), joint pain, and CRP. Percentage of participants achieving ACR20 response=(number of ACR20 responders) /(number of participants treated) * 100. All NR at Week 16 as well as all participants who discontinued study treatment at any time for any reason were defined as NR starting at that time-point and going forward, including Week 52 endpoint.

End point type	Secondary

End point timeframe:

Baseline through 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	330[80]	332[81]	335[82]	
Units: percentage of participants				
number (not applicable)	7.9	9.6	10.7	

Notes:

[80] - All randomized participants with evaluable ACR20 responder data.

[81] - All randomized participants with evaluable ACR20 responder data.

[82] - All randomized participants with evaluable ACR20 responder data.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to ACR20 response

End point title	Time to ACR20 response

End point description:

ACR Responder Index: Composite of clinical, laboratory, and functional measures of rheumatoid arthritis (RA). ACR20 Responder: had ≥20% improvement from baseline in both 68 tender and 66 swollen joint counts and ≥20% improvement in at least 3 of 5 criteria: participant's and physician's global assessment of disease activity, HAQ-DI (which measured participants' perceived degree of difficulty performing daily activities), joint pain, and CRP. The Kaplan-Meier was used to estimate time to ACR20 response over the Treatment Period (52 weeks). Time to ACR20 response = (Date of the first post-baseline visit during the Treatment Period meeting ACR20 response criteria - Date of first injection of study treatment + 1) / 7. Week 16 NR are counted as responders if they responded prior to Week 16. Otherwise, they are censored at the date of the Week 16 injection. All participants ongoing at Week 52 and had not yet responded are censored at the date of the Week 52 visit.

End point type	Secondary

End point timeframe:

Baseline through 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	327[83]	327[84]	329[85]	
Units: weeks				
median (confidence interval 95%)	16.1 (12.1 to 16.4)	16.1 (12.3 to 20.0)	20.1 (16.4 to 24.7)	

Notes:

[83] - All randomized participants with evaluable ACR20 responder data.

[84] - All randomized participants with evaluable ACR20 responder data.

[85] - All randomized participants with evaluable ACR20 responder data.

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in CRP

End point title	Change from baseline in CRP

End point description:

CRP is an indicator of inflammation. A negative change indicated an improvement in the participant's condition. LS means were calculated using ANCOVA with treatment and region as fixed factors and baseline as a covariate.

End point type	Secondary

End point timeframe:

Baseline, 24 weeks and 52 weeks

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	329[86]	328[87]	334[88]	
Units: milligrams/liter (mg/L)				
least squares mean (standard error)				
Week 24	-3.30 (± 0.83)	-2.03 (± 0.84)	-0.54 (± 0.83)	
Week 52	-1.72 (± 0.96)	-2.04 (± 0.97)	-0.40 (± 0.96)	

Notes:

[86] - All randomized participants with evaluable CRP data.

[87] - All randomized participants with evaluable CRP data.

[88] - All randomized participants with evaluable CRP data.

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Number of participants who died during post-Treatment follow-Up period

End point title	Number of participants who died during post-Treatment follow-Up period

End point description:

End point type	Other pre-specified

End point timeframe:

Discontinuation from study treatment up to 48 weeks during follow-up period

End point values	120 mg LY2127399	90 mg LY2127399	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	293[89]	303[90]	307[91]	
Units: participants				
number (not applicable)	0	1	2	

Notes:

[89] - All randomized participants who received study drug and entered follow up period.

[90] - All randomized participants who received study drug and entered follow up period.

[91] - All randomized participants who received study drug and entered follow up period.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Entire Study	
Adverse event reporting additional description:	
H9B-MC-BCDM	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	16.0

Reporting groups	
Reporting group title	LY 120 mg Q4W, Randomized Treatment Period 1
Reporting group description: -	
Reporting group title	LY 90 mg Q2W, Randomized Treatment Period 1
Reporting group description: -	
Reporting group title	Placebo, Randomized Treatment Period 1
Reporting group description: -	
Reporting group title	LY 120 mg Q4W to LY 90 mg Q2W (Week 16), Rescue Period
Reporting group description: -	
Reporting group title	LY 90 mg Q2W, Rescue Period
Reporting group description: -	
Reporting group title	Placebo to LY 90 mg Q2W (Week 16), Rescue Period
Reporting group description: -	
Reporting group title	LY 120 mg Q4W, Treatment Period 2
Reporting group description: -	
Reporting group title	LY 90 mg Q2W, Treatment Period 2
Reporting group description: -	
Reporting group title	Placebo to LY 120 mg Q4W (Week 52), Treatment Period 2
Reporting group description: -	
Reporting group title	Placebo to LY 90 mg Q2W (Week 52), Treatment Period 2
Reporting group description: -	
Reporting group title	LY 120 mg Q4W to LY 90 mg Q2W (Week 16), Treatment Period 2
Reporting group description: -	
Reporting group title	Placebo to LY 90 mg Q2W (Week 16), Treatment Period 2
Reporting group description: -	
Reporting group title	LY 120 mg Q4W, Follow-up Period
Reporting group description: -	
Reporting group title	LY 90 mg Q2W, Follow-up Period
Reporting group description: -	
Reporting group title	Placebo to LY 120 mg Q4W (Week 52), Follow-up Period
Reporting group description: -	
Reporting group title	Placebo to LY 90 mg Q2W (Week 52), Follow-up Period
Reporting group description: -	
Reporting group title	LY 120 mg Q4W to LY 90 mg Q2W (Week 16), Follow-up Period
Reporting group description: -	
Reporting group title	Placebo to LY 90 mg Q2W (Week 16), Follow-up Period
Reporting group description: -	
Reporting group title	Placebo, Follow-up Period

Reporting group description: -

Serious adverse events	LY 120 mg Q4W, Randomized Treatment Period 1	LY 90 mg Q2W, Randomized Treatment Period 1	Placebo, Randomized Treatment Period 1
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 345 (5.51%)	17 / 345 (4.93%)	17 / 348 (4.89%)
number of deaths (all causes)	2	0	1
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
b-cell lymphoma stage i			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (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
basal cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bladder transitional cell carcinoma stage iii			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervix carcinoma			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed[1]	0 / 294 (0.00%)	1 / 289 (0.35%)	0 / 291 (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
intraductal proliferative breast lesion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastatic gastric cancer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
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 16.0			
subjects affected / exposed[2]	0 / 294 (0.00%)	1 / 289 (0.35%)	0 / 291 (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
rectal adenocarcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
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			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
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 16.0			
subjects affected / exposed[3]	1 / 294 (0.34%)	0 / 289 (0.00%)	0 / 291 (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			
deep vein thrombosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (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
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral ischaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (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
General disorders and administration site conditions			
death			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device dislocation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
drug hypersensitivity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
menorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[4]	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vaginal haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[5]	1 / 294 (0.34%)	0 / 289 (0.00%)	0 / 291 (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
Respiratory, thoracic and mediastinal disorders			
acute pulmonary oedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
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 respiratory failure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
interstitial lung disease			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	0 / 348 (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 disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
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 deviation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	0 / 348 (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
obliterative bronchiolitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (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
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mental status changes			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stress			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
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			
femoral neck fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
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 16.0			
subjects affected / exposed	1 / 345 (0.29%)	1 / 345 (0.29%)	0 / 348 (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
foot fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
head injury			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	0 / 348 (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 dislocation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	0 / 348 (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 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
multiple injuries			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	0 / 348 (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
pubis fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radius fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal compression fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	1 / 348 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

synovial rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	2 / 345 (0.58%)	0 / 348 (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
Cardiac disorders			
acute myocardial infarction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arrhythmia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiogenic shock			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
congestive cardiomyopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery insufficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
myocardial infarction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	2 / 348 (0.57%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
sick sinus syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebral atrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral small vessel ischaemic disease			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
convulsion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
encephalopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	0 / 348 (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
hemiparesis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar radiculopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (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

presyncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radiculitis lumbosacral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	0 / 348 (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
syncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	0 / 348 (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
transient ischaemic attack			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (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 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
iron deficiency anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancytopenia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
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			
ulcerative keratitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
gastric haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (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
gastric ulcer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hiatus hernia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mechanical ileus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	0 / 348 (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
pancreatitis acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	1 / 345 (0.29%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancreatitis chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	0 / 348 (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
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	0 / 348 (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
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cholelithiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
calculus ureteric			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
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 16.0			
subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
renal failure acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (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 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot deformity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	0 / 348 (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
intervertebral disc protrusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (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
monarthritis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	1 / 345 (0.29%)	0 / 348 (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 16.0			
subjects affected / exposed	1 / 345 (0.29%)	1 / 345 (0.29%)	4 / 348 (1.15%)
occurrences causally related to treatment / all	0 / 1	0 / 1	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spinal column stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spondylolisthesis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (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 16.0			

subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device related infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (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
enteritis infectious			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (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
gastroenteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
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 16.0			
subjects affected / exposed	2 / 345 (0.58%)	1 / 345 (0.29%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	2 / 2	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infective tenosynovitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (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			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
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 procedural infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pseudomembranous colitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyelonephritis acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	0 / 348 (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
sepsis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (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			
diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (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	LY 120 mg Q4W to LY 90 mg Q2W (Week 16), Rescue Period	LY 90 mg Q2W, Rescue Period	Placebo to LY 90 mg Q2W (Week 16), Rescue Period
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 58 (5.17%)	3 / 62 (4.84%)	2 / 90 (2.22%)
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)			
b-cell lymphoma stage i			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
basal cell carcinoma			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bladder transitional cell carcinoma stage iii			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervix carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[1]	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intraductal proliferative breast lesion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastatic gastric cancer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			

subjects affected / exposed[2]	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal adenocarcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed[3]	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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			
deep vein thrombosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral ischaemia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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			
death			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device dislocation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	1 / 90 (1.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
drug hypersensitivity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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			
menorrhagia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed[4]	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vaginal haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[5]	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 pulmonary oedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 respiratory failure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 deviation			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obliterative bronchiolitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mental status changes			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stress			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	0 / 90 (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
suicide attempt			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	0 / 90 (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
Injury, poisoning and procedural complications			
femoral neck fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
head injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 dislocation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			

subjects affected / exposed	0 / 58 (0.00%)	1 / 62 (1.61%)	0 / 90 (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
multiple injuries			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pubis fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	0 / 90 (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
synovial rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arrhythmia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiogenic shock			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
congestive cardiomyopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery insufficiency			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sick sinus syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	1 / 62 (1.61%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebral atrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral small vessel ischaemic disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
convulsion			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
encephalopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hemiparesis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar radiculopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
presyncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radiculitis lumbosacral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

syncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
iron deficiency anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancytopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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			
ulcerative keratitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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			
gastric haemorrhage			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hiatus hernia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mechanical ileus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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			
calculus ureteric			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	0 / 90 (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
nephrolithiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 failure acute			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot deformity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
monarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			

subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	0 / 90 (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 column stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spondylolisthesis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device related infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
enteritis infectious			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	1 / 62 (1.61%)	0 / 90 (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
herpes zoster			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infective tenosynovitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	1 / 90 (1.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post procedural infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pseudomembranous colitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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 16.0			

subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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			
diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
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	LY 120 mg Q4W, Treatment Period 2	LY 90 mg Q2W, Treatment Period 2	Placebo to LY 120 mg Q4W (Week 52), Treatment Period 2
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 57 (1.75%)	1 / 73 (1.37%)	2 / 27 (7.41%)
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)			
b-cell lymphoma stage i			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
basal cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bladder transitional cell carcinoma stage iii			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervix carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[1]	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intraductal proliferative breast lesion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastatic gastric cancer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed[2]	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal adenocarcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed[3]	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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			
deep vein thrombosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral ischaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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			
death			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device dislocation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
drug hypersensitivity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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			
menorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[4]	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vaginal haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[5]	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 pulmonary oedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 respiratory failure			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 deviation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obliterative bronchiolitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mental status changes			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stress			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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			
femoral neck fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	2 / 27 (7.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot fracture			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
head injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 dislocation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
multiple injuries			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pubis fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
tendon rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arrhythmia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiogenic shock			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
congestive cardiomyopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery insufficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sick sinus syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebral atrophy			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral small vessel ischaemic disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
convulsion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
encephalopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hemiparesis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar radiculopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
presyncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
radiculitis lumbosacral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			

subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
iron deficiency anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	1 / 73 (1.37%)	0 / 27 (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
pancytopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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			
ulcerative keratitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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			
gastric haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hiatus hernia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mechanical ileus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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			
calculus ureteric			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 failure acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot deformity			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
monarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 column stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spondylolisthesis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	1 / 57 (1.75%)	0 / 73 (0.00%)	0 / 27 (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
device related infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
enteritis infectious			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			

subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infective tenosynovitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 procedural infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pseudomembranous colitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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			
diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
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	Placebo to LY 90 mg Q2W (Week 52), Treatment Period 2	LY 120 mg Q4W to LY 90 mg Q2W (Week 16), Treatment Period 2	Placebo to LY 90 mg Q2W (Week 16), Treatment Period 2
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 31 (3.23%)	0 / 13 (0.00%)	0 / 22 (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)			

b-cell lymphoma stage i			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
basal cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bladder transitional cell carcinoma stage iii			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 31 (3.23%)	0 / 13 (0.00%)	0 / 22 (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
breast cancer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervix carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[1]	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intraductal proliferative breast lesion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastatic gastric cancer			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed[2]	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal adenocarcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed[3]	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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			
deep vein thrombosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral ischaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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			
death			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device dislocation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
drug hypersensitivity			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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			
menorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[4]	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vaginal haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[5]	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 pulmonary oedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 respiratory failure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 disorder			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 deviation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obliterative bronchiolitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mental status changes			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stress			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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			
femoral neck fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
head injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 dislocation			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
multiple injuries			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pubis fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

tendon rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arrhythmia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiogenic shock			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
congestive cardiomyopathy			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery insufficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sick sinus syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebral atrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral small vessel ischaemic disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
convulsion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
encephalopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hemiparesis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar radiculopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
presyncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

radiculitis lumbosacral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
iron deficiency anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancytopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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			
ulcerative keratitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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			
gastric haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hiatus hernia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mechanical ileus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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			
calculus ureteric			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 failure acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot deformity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
monarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 column stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spondylolisthesis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device related infection			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
enteritis infectious			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infective tenosynovitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

peritonitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 procedural infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pseudomembranous colitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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			
diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
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	LY 120 mg Q4W, Follow-up Period	LY 90 mg Q2W, Follow-up Period	Placebo to LY 120 mg Q4W (Week 52), Follow-up Period
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 241 (3.32%)	11 / 303 (3.63%)	1 / 27 (3.70%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
b-cell lymphoma stage i			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
basal cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
bladder transitional cell carcinoma stage iii			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervix carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[1]	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intraductal proliferative breast lesion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	0 / 303 (0.00%)	0 / 27 (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
metastatic gastric cancer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	0 / 303 (0.00%)	0 / 27 (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 16.0			
subjects affected / exposed[2]	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal adenocarcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed[3]	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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			
deep vein thrombosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral ischaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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			
death			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device dislocation			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	0 / 303 (0.00%)	0 / 27 (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
Immune system disorders			
drug hypersensitivity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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			
menorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[4]	0 / 211 (0.00%)	1 / 255 (0.39%)	0 / 22 (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
vaginal haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[5]	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 pulmonary oedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 respiratory failure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	2 / 303 (0.66%)	0 / 27 (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
lung disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 deviation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obliterative bronchiolitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	1 / 27 (3.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mental status changes			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stress			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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			
femoral neck fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	1 / 303 (0.33%)	0 / 27 (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
femur fracture			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (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
head injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 dislocation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
multiple injuries			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pubis fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (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
tendon rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (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
arrhythmia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (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
atrial fibrillation			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiogenic shock			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
congestive cardiomyopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery insufficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (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
sick sinus syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nervous system disorders			
cerebral atrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral small vessel ischaemic disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
convulsion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
encephalopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hemiparesis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar radiculopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
presyncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (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
radiculitis lumbosacral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			

subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
iron deficiency anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancytopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	0 / 303 (0.00%)	0 / 27 (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
Eye disorders			
ulcerative keratitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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			
gastric haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hiatus hernia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (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
mechanical ileus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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			
calculus ureteric			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 failure acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot deformity			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
monarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (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
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	1 / 303 (0.33%)	0 / 27 (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
spinal column stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	0 / 303 (0.00%)	0 / 27 (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
spondylolisthesis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
device related infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diverticulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
enteritis infectious			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			

subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infective tenosynovitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	0 / 303 (0.00%)	0 / 27 (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
peritonitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (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
post procedural infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pseudomembranous colitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	1 / 241 (0.41%)	0 / 303 (0.00%)	0 / 27 (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
pyelonephritis chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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			
diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
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	Placebo to LY 90 mg Q2W (Week 52), Follow-up Period	LY 120 mg Q4W to LY 90 mg Q2W (Week 16), Follow-up Period	Placebo to LY 90 mg Q2W (Week 16), Follow-up Period
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 27 (3.70%)	4 / 52 (7.69%)	4 / 85 (4.71%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

b-cell lymphoma stage i			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
basal cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	0 / 85 (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
bladder transitional cell carcinoma stage iii			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
breast cancer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cervix carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[1]	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intraductal proliferative breast lesion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
metastatic gastric cancer			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed[2]	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rectal adenocarcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	0 / 85 (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
squamous cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed[3]	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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			
deep vein thrombosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peripheral ischaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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			
death			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
device dislocation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
non-cardiac chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
drug hypersensitivity			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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			
menorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[4]	0 / 24 (0.00%)	0 / 40 (0.00%)	0 / 66 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vaginal haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[5]	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 pulmonary oedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 respiratory failure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 disorder			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 deviation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
obliterative bronchiolitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pulmonary embolism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mental status changes			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
stress			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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			
femoral neck fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
head injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 dislocation			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
multiple injuries			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pubis fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
synovial rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

tendon rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
arrhythmia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
atrial fibrillation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cardiogenic shock			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
congestive cardiomyopathy			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
coronary artery insufficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
sick sinus syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebral atrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebral small vessel ischaemic disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
cerebrovascular accident			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
convulsion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
encephalopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hemiparesis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lumbar radiculopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
presyncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

radiculitis lumbosacral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
syncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
iron deficiency anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pancytopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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			
ulcerative keratitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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			
gastric haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hiatus hernia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
mechanical ileus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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			
calculus ureteric			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 failure acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot deformity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
monarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 column stenosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
spondylolisthesis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	0 / 85 (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
device related infection			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	0 / 85 (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
diverticulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
enteritis infectious			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
infective tenosynovitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

peritonitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
post procedural infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pseudomembranous colitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	1 / 27 (3.70%)	0 / 52 (0.00%)	0 / 85 (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
pyelonephritis chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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			
diabetes mellitus inadequate control			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
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	Placebo, Follow-up Period		
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 168 (7.14%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
b-cell lymphoma stage i			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
basal cell carcinoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
bladder transitional cell carcinoma stage iii			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
breast cancer				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 168 (0.60%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
cervix carcinoma				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed[1]	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
intraductal proliferative breast lesion				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
metastatic gastric cancer				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ovarian cancer				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed[2]	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
rectal adenocarcinoma				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

squamous cell carcinoma				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 168 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
uterine leiomyoma				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed[3]	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
deep vein thrombosis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hypotension				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
peripheral ischaemia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
death				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
device dislocation				

alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
non-cardiac chest pain				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pyrexia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
drug hypersensitivity				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
menorrhagia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed[4]	0 / 146 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
vaginal haemorrhage				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed[5]	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				

acute pulmonary oedema				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 168 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
chronic respiratory failure				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (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 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
lung disorder				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 168 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
nasal septum deviation				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
obliterative bronchiolitis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pulmonary embolism				
alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
mental status changes			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
stress			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
suicide attempt			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
femoral neck fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
femur fracture			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
foot fracture				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
head injury				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
joint dislocation				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
joint injury				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
multiple injuries				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pubis fracture				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

radius fracture				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (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 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
synovial rupture				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
tendon rupture				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (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 16.0				
subjects affected / exposed	1 / 168 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
arrhythmia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
atrial fibrillation				
alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	1 / 168 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
cardiac failure chronic				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
cardiogenic shock				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
congestive cardiomyopathy				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 168 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
coronary artery insufficiency				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
myocardial infarction				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sick sinus syndrome				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Nervous system disorders			
cerebral atrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
cerebral small vessel ischaemic disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
cerebrovascular accident			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
convulsion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
encephalopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
hemiparesis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
lumbar radiculopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
presyncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
radiculitis lumbosacral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
syncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (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 16.0			
subjects affected / exposed	0 / 168 (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 16.0			

subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
iron deficiency anaemia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pancytopenia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				
ulcerative keratitis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
gastric haemorrhage				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
gastric ulcer				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
hiatus hernia				
alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
mechanical ileus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pancreatitis acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pancreatitis chronic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
cholelithiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
calculus ureteric			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
nephrolithiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
renal failure acute			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (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 16.0			
subjects affected / exposed	1 / 168 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
foot deformity			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 168 (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 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
monarthritis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
osteoarthritis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
rheumatoid arthritis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	3 / 168 (1.79%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
spinal column stenosis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
spondylolisthesis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
cellulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
device related infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 168 (0.60%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
diverticulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
enteritis infectious			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
gastroenteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 168 (0.60%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
herpes zoster			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
infective tenosynovitis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 168 (0.60%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
influenza				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
peritonitis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pneumonia				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
post procedural infection				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pseudomembranous colitis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

pyelonephritis acute				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
pyelonephritis chronic				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
sepsis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (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 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
diabetes mellitus inadequate control				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (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.
[5] - 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	LY 120 mg Q4W, Randomized Treatment Period 1	LY 90 mg Q2W, Randomized Treatment Period 1	Placebo, Randomized Treatment Period 1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	137 / 345 (39.71%)	117 / 345 (33.91%)	129 / 348 (37.07%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
neuroma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
ovarian germ cell teratoma benign			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[6]	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
uterine leiomyoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[7]	1 / 294 (0.34%)	1 / 289 (0.35%)	0 / 291 (0.00%)
occurrences (all)	1	1	0
Vascular disorders			
haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	12 / 345 (3.48%)	3 / 345 (0.87%)	7 / 348 (2.01%)
occurrences (all)	13	3	7
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	2 / 345 (0.58%)	0 / 348 (0.00%)
occurrences (all)	1	2	0

General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 345 (1.16%)	4 / 345 (1.16%)	1 / 348 (0.29%)
occurrences (all)	5	5	1
malaise			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	2 / 348 (0.57%)
occurrences (all)	1	0	2
oedema peripheral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 345 (0.87%)	1 / 345 (0.29%)	3 / 348 (0.86%)
occurrences (all)	3	1	3
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 345 (0.87%)	3 / 345 (0.87%)	1 / 348 (0.29%)
occurrences (all)	3	3	1
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[8]	0 / 51 (0.00%)	1 / 56 (1.79%)	0 / 57 (0.00%)
occurrences (all)	0	1	0
metrorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[9]	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
uterine prolapse			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[10]	1 / 294 (0.34%)	0 / 289 (0.00%)	0 / 291 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	7 / 345 (2.03%)	3 / 345 (0.87%)	5 / 348 (1.44%)
occurrences (all)	8	3	5
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 345 (0.87%)	1 / 345 (0.29%)	1 / 348 (0.29%)
occurrences (all)	3	1	1
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 345 (0.58%)	1 / 345 (0.29%)	1 / 348 (0.29%)
occurrences (all)	2	1	1
insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	7 / 345 (2.03%)	3 / 345 (0.87%)	3 / 348 (0.86%)
occurrences (all)	7	3	3
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 345 (1.16%)	2 / 345 (0.58%)	6 / 348 (1.72%)
occurrences (all)	4	2	6
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences (all)	0	0	1
blood glucose increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 345 (0.58%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	2	0	0
blood potassium decreased			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	2 / 345 (0.58%)	1 / 348 (0.29%)
occurrences (all)	0	2	1
haemoglobin decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 345 (0.58%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences (all)	2	0	1
liver function test abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	1	0	0
white blood cell count decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	1 / 348 (0.29%)
occurrences (all)	0	1	1
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 345 (0.87%)	1 / 345 (0.29%)	4 / 348 (1.15%)
occurrences (all)	3	1	4
ligament sprain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 345 (0.58%)	1 / 345 (0.29%)	2 / 348 (0.57%)
occurrences (all)	2	1	2
muscle strain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
radius fracture			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
tendon injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 345 (0.58%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
carpal tunnel syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 345 (0.58%)	0 / 345 (0.00%)	2 / 348 (0.57%)
occurrences (all)	2	0	3
dizziness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 345 (1.16%)	6 / 345 (1.74%)	5 / 348 (1.44%)
occurrences (all)	4	6	5
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	7 / 345 (2.03%)	6 / 345 (1.74%)	3 / 348 (0.86%)
occurrences (all)	10	6	3
hypoaesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	2 / 348 (0.57%)
occurrences (all)	0	0	2
migraine			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	2 / 345 (0.58%)	0 / 348 (0.00%)
occurrences (all)	1	2	0
paraesthesia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences (all)	1	0	1
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	8 / 345 (2.32%)	6 / 345 (1.74%)	11 / 348 (3.16%)
occurrences (all)	8	6	11
leukocytosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	1	0	0
lymphopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 345 (1.45%)	1 / 345 (0.29%)	2 / 348 (0.57%)
occurrences (all)	6	2	2
Eye disorders			
cataract			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 345 (0.58%)	2 / 345 (0.58%)	1 / 348 (0.29%)
occurrences (all)	2	2	1
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 345 (0.58%)	2 / 345 (0.58%)	1 / 348 (0.29%)
occurrences (all)	2	2	1
constipation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 345 (1.16%)	3 / 345 (0.87%)	6 / 348 (1.72%)
occurrences (all)	4	3	6
diarrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	7 / 345 (2.03%)	9 / 345 (2.61%)	5 / 348 (1.44%)
occurrences (all)	7	9	6
dyspepsia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	3 / 345 (0.87%)	1 / 345 (0.29%)	2 / 348 (0.57%)
occurrences (all)	3	1	2
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 345 (0.58%)	1 / 345 (0.29%)	5 / 348 (1.44%)
occurrences (all)	2	1	5
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	7 / 345 (2.03%)	7 / 345 (2.03%)	3 / 348 (0.86%)
occurrences (all)	7	11	3
stomatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 345 (0.87%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences (all)	4	0	1
Hepatobiliary disorders			
hepatic function abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 345 (0.87%)	1 / 345 (0.29%)	2 / 348 (0.57%)
occurrences (all)	3	1	2
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	3 / 345 (0.87%)	1 / 348 (0.29%)
occurrences (all)	1	3	1
rash			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 345 (1.74%)	3 / 345 (0.87%)	5 / 348 (1.44%)
occurrences (all)	6	3	6
Renal and urinary disorders			
pollakiuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
stress urinary incontinence			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 345 (1.74%)	9 / 345 (2.61%)	7 / 348 (2.01%)
occurrences (all)	9	10	7
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	10 / 345 (2.90%)	6 / 345 (1.74%)	5 / 348 (1.44%)
occurrences (all)	10	6	5
bunion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences (all)	0	0	1
foot deformity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	1 / 345 (0.29%)	1 / 348 (0.29%)
occurrences (all)	1	1	1
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 345 (0.87%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences (all)	3	0	1
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 345 (1.16%)	1 / 345 (0.29%)	3 / 348 (0.86%)
occurrences (all)	5	1	3
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	12 / 345 (3.48%)	19 / 345 (5.51%)	15 / 348 (4.31%)
occurrences (all)	14	20	18
tenosynovitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 345 (0.00%)	1 / 345 (0.29%)	0 / 348 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	8 / 345 (2.32%)	8 / 345 (2.32%)	11 / 348 (3.16%)
occurrences (all)	8	8	11
candidiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	1 / 345 (0.29%)	0 / 348 (0.00%)
occurrences (all)	2	1	0
cystitis bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	2 / 345 (0.58%)	2 / 348 (0.57%)
occurrences (all)	1	2	2
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	2 / 345 (0.58%)	8 / 348 (2.30%)
occurrences (all)	1	2	8
nasopharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	20 / 345 (5.80%)	15 / 345 (4.35%)	25 / 348 (7.18%)
occurrences (all)	25	22	34
onychomycosis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	7 / 345 (2.03%)	4 / 345 (1.16%)	5 / 348 (1.44%)
occurrences (all)	7	4	5
pulpitis dental			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	18 / 345 (5.22%)	20 / 345 (5.80%)	18 / 348 (5.17%)
occurrences (all)	21	21	20
upper respiratory tract infection bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences (all)	0	0	1
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	10 / 345 (2.90%)	6 / 345 (1.74%)	5 / 348 (1.44%)
occurrences (all)	12	8	6
viral infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	2 / 348 (0.57%)
occurrences (all)	0	0	2
vulvovaginitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[11]	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 345 (0.29%)	1 / 345 (0.29%)	1 / 348 (0.29%)
occurrences (all)	1	1	1
hypercholesterolaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	0 / 345 (0.00%)	1 / 348 (0.29%)
occurrences (all)	1	0	1
hyperglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 345 (0.29%)	1 / 345 (0.29%)	0 / 348 (0.00%)
occurrences (all)	1	1	0
hyperlipidaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
hypoalbuminaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
hyponatraemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 345 (0.00%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 345 (1.16%)	0 / 345 (0.00%)	0 / 348 (0.00%)
occurrences (all)	4	0	0

Non-serious adverse events	LY 120 mg Q4W to LY 90 mg Q2W (Week 16), Rescue Period	LY 90 mg Q2W, Rescue Period	Placebo to LY 90 mg Q2W (Week 16), Rescue Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 58 (37.93%)	25 / 62 (40.32%)	20 / 90 (22.22%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
neuroma			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	1 / 90 (1.11%)
occurrences (all)	0	0	1
ovarian germ cell teratoma benign			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[6]	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
uterine leiomyoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[7]	1 / 44 (2.27%)	0 / 57 (0.00%)	0 / 69 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 58 (3.45%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	2	0	0
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	2 / 62 (3.23%)	0 / 90 (0.00%)
occurrences (all)	0	2	0
malaise			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	1 / 90 (1.11%)
occurrences (all)	1	0	2
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[8]	0 / 14 (0.00%)	1 / 5 (20.00%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
metrorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[9]	1 / 44 (2.27%)	0 / 57 (0.00%)	0 / 69 (0.00%)
occurrences (all)	1	0	0
uterine prolapse			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[10]	1 / 44 (2.27%)	0 / 57 (0.00%)	0 / 69 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	2 / 90 (2.22%)
occurrences (all)	1	0	2
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	1 / 90 (1.11%)
occurrences (all)	0	0	1
depression			
alternative dictionary used:			

MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	2 / 62 (3.23%)	1 / 90 (1.11%)
occurrences (all)	0	2	1
insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	1 / 90 (1.11%)
occurrences (all)	0	0	1
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	1	0	0
blood glucose increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	1	0	0
blood potassium decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 58 (3.45%)	1 / 62 (1.61%)	0 / 90 (0.00%)
occurrences (all)	2	1	0
haemoglobin decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	1	0	0
liver function test abnormal			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 58 (1.72%)	1 / 62 (1.61%)	0 / 90 (0.00%)
occurrences (all)	1	1	0
white blood cell count decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	1 / 62 (1.61%)	0 / 90 (0.00%)
occurrences (all)	0	1	0
ligament sprain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	1 / 90 (1.11%)
occurrences (all)	0	0	1
radius fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
tendon injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	1 / 90 (1.11%)
occurrences (all)	0	0	1
Nervous system disorders			

carpal tunnel syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	1 / 90 (1.11%)
occurrences (all)	0	0	1
dizziness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	1	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	1	0	0
migraine			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	1 / 62 (1.61%)	0 / 90 (0.00%)
occurrences (all)	0	1	0
paraesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	5 / 90 (5.56%)
occurrences (all)	1	0	5
leukocytosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	1 / 62 (1.61%)	0 / 90 (0.00%)
occurrences (all)	1	1	0
lymphopenia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
cataract			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	2 / 62 (3.23%)	0 / 90 (0.00%)
occurrences (all)	0	3	0
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	1 / 90 (1.11%)
occurrences (all)	1	0	1
constipation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	1 / 62 (1.61%)	0 / 90 (0.00%)
occurrences (all)	0	1	0
diarrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	1 / 62 (1.61%)	0 / 90 (0.00%)
occurrences (all)	1	1	0
dyspepsia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 58 (3.45%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	2	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 58 (3.45%)	1 / 62 (1.61%)	1 / 90 (1.11%)
occurrences (all)	2	1	1
stomatitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
hepatic function abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	1 / 62 (1.61%)	0 / 90 (0.00%)
occurrences (all)	0	1	0
rash			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
pollakiuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	1	0	0
stress urinary incontinence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 58 (3.45%)	0 / 62 (0.00%)	1 / 90 (1.11%)
occurrences (all)	8	0	1
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	1	0	0
bunion			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
foot deformity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 58 (3.45%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	2	0	0
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 58 (3.45%)	1 / 62 (1.61%)	0 / 90 (0.00%)
occurrences (all)	3	1	0
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 58 (5.17%)	5 / 62 (8.06%)	0 / 90 (0.00%)
occurrences (all)	3	5	0
tenosynovitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	3 / 62 (4.84%)	1 / 90 (1.11%)
occurrences (all)	1	3	1
candidiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	1 / 90 (1.11%)
occurrences (all)	0	0	1
cystitis bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	1 / 90 (1.11%)
occurrences (all)	0	0	1
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	1 / 62 (1.61%)	1 / 90 (1.11%)
occurrences (all)	0	1	1
nasopharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 58 (3.45%)	3 / 62 (4.84%)	2 / 90 (2.22%)
occurrences (all)	2	4	2
onychomycosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	1 / 90 (1.11%)
occurrences (all)	0	0	1
pulpitis dental			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	1 / 62 (1.61%)	2 / 90 (2.22%)
occurrences (all)	0	1	2

upper respiratory tract infection bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	1 / 62 (1.61%)	1 / 90 (1.11%)
occurrences (all)	1	1	1
viral infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
vulvovaginitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[11]	1 / 44 (2.27%)	0 / 57 (0.00%)	0 / 69 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	1 / 62 (1.61%)	0 / 90 (0.00%)
occurrences (all)	1	1	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	1 / 62 (1.61%)	0 / 90 (0.00%)
occurrences (all)	0	1	0
hyperglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 58 (1.72%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	1	0	0
hypoalbuminaemia			
alternative dictionary used:			

MedDRA 16.0			
subjects affected / exposed	2 / 58 (3.45%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	2	0	0
hyponatraemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	0 / 62 (0.00%)	0 / 90 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 58 (0.00%)	1 / 62 (1.61%)	1 / 90 (1.11%)
occurrences (all)	0	2	1

Non-serious adverse events	LY 120 mg Q4W, Treatment Period 2	LY 90 mg Q2W, Treatment Period 2	Placebo to LY 120 mg Q4W (Week 52), Treatment Period 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 57 (38.60%)	20 / 73 (27.40%)	7 / 27 (25.93%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
neuroma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
ovarian germ cell teratoma benign			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[6]	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
uterine leiomyoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[7]	1 / 51 (1.96%)	1 / 62 (1.61%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Vascular disorders			
haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 57 (3.51%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	2	0	0
hypertension			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	2 / 57 (3.51%)	2 / 73 (2.74%)	1 / 27 (3.70%)
occurrences (all)	2	2	1
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
malaise			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[8]	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
metrorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[9]	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
uterine prolapse			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed[10]	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 57 (1.75%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	2 / 73 (2.74%)	0 / 27 (0.00%)
occurrences (all)	0	2	0
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	3 / 73 (4.11%)	0 / 27 (0.00%)
occurrences (all)	0	3	0
insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 57 (3.51%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	2	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
blood glucose increased			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
blood potassium decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	1 / 73 (1.37%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
haemoglobin decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
liver function test abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
white blood cell count decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	1 / 73 (1.37%)	1 / 27 (3.70%)
occurrences (all)	0	1	1
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	2 / 73 (2.74%)	0 / 27 (0.00%)
occurrences (all)	0	2	0
ligament sprain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 57 (3.51%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	2	0	0
muscle strain			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
radius fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
tendon injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
carpal tunnel syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 57 (3.51%)	1 / 73 (1.37%)	0 / 27 (0.00%)
occurrences (all)	2	1	0
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	1 / 73 (1.37%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
hypoaesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	1 / 73 (1.37%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
migraine			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 57 (0.00%)	2 / 73 (2.74%)	0 / 27 (0.00%)
occurrences (all)	0	2	0
paraesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 57 (1.75%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
leukocytosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
lymphopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
cataract			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 57 (1.75%)	3 / 73 (4.11%)	0 / 27 (0.00%)
occurrences (all)	1	3	0
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 57 (5.26%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	3	0	0
diarrhoea			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 57 (1.75%)	0 / 73 (0.00%)	1 / 27 (3.70%)
occurrences (all)	1	0	1
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 57 (1.75%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
stomatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
hepatic function abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 57 (1.75%)	2 / 73 (2.74%)	0 / 27 (0.00%)
occurrences (all)	1	2	0
rash			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 57 (3.51%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	2	0	0
Renal and urinary disorders			
pollakiuria			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
stress urinary incontinence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 57 (1.75%)	2 / 73 (2.74%)	0 / 27 (0.00%)
occurrences (all)	1	2	0
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 57 (3.51%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	2	0	0
bunion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
foot deformity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 57 (1.75%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	1 / 73 (1.37%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	5 / 57 (8.77%)	3 / 73 (4.11%)	0 / 27 (0.00%)
occurrences (all)	5	3	0
tenosynovitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 57 (1.75%)	1 / 73 (1.37%)	1 / 27 (3.70%)
occurrences (all)	1	1	1
candidiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
cellulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
cystitis bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
herpes zoster			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 57 (3.51%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	2	0	0
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 57 (1.75%)	3 / 73 (4.11%)	1 / 27 (3.70%)
occurrences (all)	1	3	1
onychomycosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 57 (1.75%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
upper respiratory tract infection bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 57 (1.75%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
viral infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
vulvovaginitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[11]	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
hypercholesterolaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
hyperglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
hyperlipidaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
hypoalbuminaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
hyponatraemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	0 / 73 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 57 (0.00%)	1 / 73 (1.37%)	0 / 27 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	Placebo to LY 90 mg Q2W (Week 52), Treatment Period 2	LY 120 mg Q4W to LY 90 mg Q2W (Week 16), Treatment Period 2	Placebo to LY 90 mg Q2W (Week 16), Treatment Period 2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 31 (12.90%)	7 / 13 (53.85%)	9 / 22 (40.91%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

neuroma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
ovarian germ cell teratoma benign			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[6]	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
uterine leiomyoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[7]	0 / 27 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
malaise			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[8]	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
metrorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[9]	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
uterine prolapse			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[10]	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1

depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	2
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
blood glucose increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	1 / 13 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
blood potassium decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 31 (3.23%)	0 / 13 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
haemoglobin decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	1 / 13 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
liver function test abnormal			
alternative dictionary used:			

MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	1 / 13 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
white blood cell count decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	1 / 13 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 31 (3.23%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
ligament sprain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
radius fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
tendon injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	1 / 13 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

carpal tunnel syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
dizziness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
hypoaesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	1 / 13 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
migraine			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
paraesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
leukocytosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
lymphopenia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
cataract			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
constipation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 31 (3.23%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
diarrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
stomatitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 31 (3.23%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
hepatic function abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
pollakiuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
stress urinary incontinence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
bunion			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
foot deformity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	2 / 13 (15.38%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
tenosynovitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
candidiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
cystitis bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
onychomycosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	1 / 13 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
pharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
pulpitis dental			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1

upper respiratory tract infection bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 31 (3.23%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
viral infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
vulvovaginitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[11]	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	1 / 13 (7.69%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
hypoalbuminaemia			
alternative dictionary used:			

MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
hyponatraemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 31 (0.00%)	0 / 13 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2

Non-serious adverse events	LY 120 mg Q4W, Follow-up Period	LY 90 mg Q2W, Follow-up Period	Placebo to LY 120 mg Q4W (Week 52), Follow-up Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	43 / 241 (17.84%)	39 / 303 (12.87%)	6 / 27 (22.22%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
neuroma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
ovarian germ cell teratoma benign			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[6]	0 / 211 (0.00%)	0 / 255 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
uterine leiomyoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[7]	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 241 (0.41%)	2 / 303 (0.66%)	0 / 27 (0.00%)
occurrences (all)	1	2	0
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
malaise			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
oedema peripheral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	2 / 303 (0.66%)	0 / 27 (0.00%)
occurrences (all)	0	3	0
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[8]	0 / 30 (0.00%)	1 / 48 (2.08%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
metrorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[9]	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
uterine prolapse			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed[10]	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 241 (1.24%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	3	0	0
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	1	1	0
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
blood glucose increased			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 241 (0.41%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
blood potassium decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
haemoglobin decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
liver function test abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
white blood cell count decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
muscle strain			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
radius fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
tendon injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
carpal tunnel syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 241 (0.83%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	2	1	0
hypoaesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
migraine			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
paraesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	1	1	0
leukocytosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
lymphopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 241 (0.83%)	1 / 303 (0.33%)	1 / 27 (3.70%)
occurrences (all)	2	1	1
Eye disorders			
cataract			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	1	1	0
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
constipation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 241 (1.24%)	2 / 303 (0.66%)	0 / 27 (0.00%)
occurrences (all)	3	2	0
diarrhoea			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	3 / 241 (1.24%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	3	1	0
dyspepsia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 241 (0.83%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	2	1	0
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	1	1	0
stomatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
hepatic function abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
pollakiuria			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 241 (0.41%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	1	1	0
stress urinary incontinence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 241 (0.83%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	2	0	0
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
bunion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
foot deformity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	5 / 241 (2.07%)	4 / 303 (1.32%)	0 / 27 (0.00%)
occurrences (all)	5	4	0
tenosynovitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	1	1	0
candidiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
cystitis bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 241 (0.83%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	2	1	0
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	2 / 303 (0.66%)	1 / 27 (3.70%)
occurrences (all)	1	2	1
nasopharyngitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	7 / 241 (2.90%)	7 / 303 (2.31%)	0 / 27 (0.00%)
occurrences (all)	8	9	0
onychomycosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 241 (0.41%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	1	0	0
pharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
pulpitis dental			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	1 / 27 (3.70%)
occurrences (all)	0	0	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 241 (1.66%)	4 / 303 (1.32%)	0 / 27 (0.00%)
occurrences (all)	4	5	0
upper respiratory tract infection bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 241 (0.83%)	3 / 303 (0.99%)	0 / 27 (0.00%)
occurrences (all)	2	3	0
viral infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
vulvovaginitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[11]	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	1 / 303 (0.33%)	0 / 27 (0.00%)
occurrences (all)	0	1	0
hypoalbuminaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
hyponatraemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 241 (0.00%)	0 / 303 (0.00%)	0 / 27 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo to LY 90 mg Q2W (Week 52), Follow-up Period	LY 120 mg Q4W to LY 90 mg Q2W (Week 16), Follow-up Period	Placebo to LY 90 mg Q2W (Week 16), Follow-up Period
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 27 (33.33%)	10 / 52 (19.23%)	10 / 85 (11.76%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

neuroma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
ovarian germ cell teratoma benign			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[6]	1 / 24 (4.17%)	0 / 40 (0.00%)	0 / 66 (0.00%)
occurrences (all)	1	0	0
uterine leiomyoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[7]	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
hypertension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 27 (3.70%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	1	0	0
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
malaise			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 27 (3.70%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	1	0	0
oedema peripheral			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences (all)	0	0	1
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 27 (3.70%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[8]	0 / 3 (0.00%)	0 / 12 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
metrorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[9]	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
uterine prolapse			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[10]	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 27 (3.70%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	1	0	0
cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences (all)	0	0	1
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0

depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	0 / 85 (0.00%)
occurrences (all)	0	1	0
blood glucose increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
blood potassium decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 27 (3.70%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	1	0	0
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
haemoglobin decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
liver function test abnormal			
alternative dictionary used:			

MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	0 / 85 (0.00%)
occurrences (all)	0	1	0
white blood cell count decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
ligament sprain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
radius fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
tendon injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 27 (3.70%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			

carpal tunnel syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences (all)	0	0	1
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	2 / 85 (2.35%)
occurrences (all)	0	0	2
hypoaesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
migraine			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
paraesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 27 (3.70%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
leukocytosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
lymphopenia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
cataract			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	2 / 52 (3.85%)	0 / 85 (0.00%)
occurrences (all)	0	2	0
constipation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
dyspepsia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences (all)	0	0	1
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	0 / 85 (0.00%)
occurrences (all)	0	1	0
stomatitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
hepatic function abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 27 (3.70%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
rash			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
pollakiuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 27 (3.70%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	1	0	0
stress urinary incontinence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences (all)	0	0	1
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	2 / 52 (3.85%)	1 / 85 (1.18%)
occurrences (all)	0	2	1
bunion			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences (all)	0	0	2
foot deformity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 27 (7.41%)	1 / 52 (1.92%)	0 / 85 (0.00%)
occurrences (all)	2	1	0
tenosynovitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
candidiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
cystitis bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
herpes zoster			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 27 (11.11%)	1 / 52 (1.92%)	0 / 85 (0.00%)
occurrences (all)	3	1	0
onychomycosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	0 / 85 (0.00%)
occurrences (all)	0	1	0
pulpitis dental			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	2 / 85 (2.35%)
occurrences (all)	0	0	2

upper respiratory tract infection bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 27 (3.70%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	1	0	0
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	1 / 85 (1.18%)
occurrences (all)	0	0	1
viral infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 27 (3.70%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	1	0	0
vulvovaginitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[11]	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	0 / 85 (0.00%)
occurrences (all)	0	1	0
hypercholesterolaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
hyperglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	1 / 52 (1.92%)	0 / 85 (0.00%)
occurrences (all)	0	1	0
hypoalbuminaemia			
alternative dictionary used:			

MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
hyponatraemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 27 (0.00%)	0 / 52 (0.00%)	0 / 85 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Placebo, Follow-up Period		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 168 (15.48%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
neuroma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
ovarian germ cell teratoma benign			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[6]	0 / 146 (0.00%)		
occurrences (all)	0		
uterine leiomyoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[7]	0 / 168 (0.00%)		
occurrences (all)	0		
Vascular disorders			
haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
hypertension			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 168 (0.60%)		
occurrences (all)	1		
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
injection site erythema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
malaise			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
oedema peripheral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 168 (0.60%)		
occurrences (all)	1		
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
benign prostatic hyperplasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[8]	0 / 22 (0.00%)		
occurrences (all)	0		
metrorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[9]	0 / 168 (0.00%)		
occurrences (all)	0		
uterine prolapse			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed[10]	0 / 168 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
anxiety			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 168 (0.60%)		
occurrences (all)	1		
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
blood glucose increased			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
blood potassium decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
haemoglobin decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
liver function test abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
white blood cell count decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 168 (0.60%)		
occurrences (all)	1		
ligament sprain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
muscle strain			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
radius fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
tendon injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
carpal tunnel syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
dizziness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 168 (0.60%)		
occurrences (all)	1		
hypoaesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
migraine			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
paraesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
leukocytosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
lymphopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
Eye disorders			
cataract			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 168 (0.60%)		
occurrences (all)	1		
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 168 (0.60%)		
occurrences (all)	1		
constipation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
diarrhoea			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 168 (0.60%)		
occurrences (all)	1		
dyspepsia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 168 (0.60%)		
occurrences (all)	1		
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 168 (1.79%)		
occurrences (all)	3		
stomatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 168 (0.60%)		
occurrences (all)	1		
Hepatobiliary disorders			
hepatic function abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
alopecia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
rash			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
pollakiuria			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 168 (0.60%)		
occurrences (all)	1		
stress urinary incontinence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
bunion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
foot deformity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
rheumatoid arthritis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	3 / 168 (1.79%)		
occurrences (all)	3		
tenosynovitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
Infections and infestations			
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 168 (0.60%)		
occurrences (all)	1		
candidiasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
cellulitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
cystitis bacterial			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
herpes zoster			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 168 (1.19%)		
occurrences (all)	2		
nasopharyngitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	5 / 168 (2.98%)			
occurrences (all)	5			
onychomycosis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences (all)	0			
pharyngitis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences (all)	0			
pulpitis dental				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences (all)	0			
upper respiratory tract infection				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	5 / 168 (2.98%)			
occurrences (all)	5			
upper respiratory tract infection bacterial				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences (all)	0			
urinary tract infection				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	2 / 168 (1.19%)			
occurrences (all)	2			
viral infection				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 168 (0.00%)			
occurrences (all)	0			
vulvovaginitis				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed[11]	0 / 168 (0.00%)			
occurrences (all)	0			

Metabolism and nutrition disorders			
diabetes mellitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
hypercholesterolaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 168 (0.60%)		
occurrences (all)	1		
hyperglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
hyperlipidaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
hypoalbuminaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
hyponatraemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 168 (0.00%)		
occurrences (all)	0		

Notes:

[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.
[9] - 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.
[10] - 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.
[11] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

This study has been terminated not based on safety concerns, but due to insufficient efficacy. Early termination led to lower than expected enrollment and was responsible for the large number of discontinuation reason as Sponsor Decision.

Notes: