Clinical trial results:
A 12-Week, Phase 2, Randomized, Double-Blind, Multicenter, Placebo Controlled Study to Investigate the Safety, Pharmacokinetics and Efficacy of ARRY-438162, Administered Orally Daily in Patients With Active Rheumatoid Arthritis Incompletely Responsive to Methotrexate

Summary

EudraCT number	2007-007859-14
Trial protocol	HU PL
Global end of trial date	07 July 2009

Results information

Result version number	v1 (current)
This version publication date	06 August 2016
First version publication date	06 August 2016

Trial information

Trial identification

Sponsor protocol code	ARRAY-162-201

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00650767
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Array BioPharma, Inc.
Sponsor organisation address	3200 Walnut Street, Boulder, United States, 80301
Public contact	Clinical Operations, Array BioPharma, Inc., +1 303-381-6604, clinicaltrials@arraybiopharma.com
Scientific contact	Clinical Operations, Array BioPharma, Inc., +1 303-381-6604, clinicaltrials@arraybiopharma.com

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	07 July 2009
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 July 2009
Global end of trial reached?	Yes
Global end of trial date	07 July 2009
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This was a Phase 2 study, involving a 12-week treatment period, designed to evaluate the effectiveness of investigational study drug ARRY-438162 in treating rheumatoid arthritis in patients on stable doses of methotrexate, and to further evaluate the safety of the study drug.

Protection of trial subjects:

This study was conducted according to International Conference on Harmonisation (ICH) guidelines concerning Good Clinical Practice (GCP), the European Union Clinical Trials Directive (2001/20/EC), the U.S. Food and Drug Administration (FDA) Code of Federal Regulations (CFR) and all applicable local, regional and national regulations.

Written informed consent to participate in the study was obtained from each patient before any study-specific procedures were performed on that patient.

Background therapy:

N/A

Evidence for comparator:

N/A

Actual start date of recruitment	04 April 2008
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 32
Country: Number of subjects enrolled	Brazil: 18
Country: Number of subjects enrolled	Hungary: 33
Country: Number of subjects enrolled	Peru: 51
Country: Number of subjects enrolled	Poland: 48
Country: Number of subjects enrolled	Romania: 18
Country: Number of subjects enrolled	United States: 1
Worldwide total number of subjects	201
EEA total number of subjects	99

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)	174
From 65 to 84 years	27
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The ARRAY-162-201 study began recruitment on 04-April-2018 (First Patient First Visit) and concluded on 07-July-2019 (Last Patient Last Visit).

This study was conducted at 36 sites in the United States, Europe and South America.

Pre-assignment

Screening details:

Participant Flow and Baseline Demographics represent the Intent-to-Treat (ITT) population, which is all patients who were randomized to a treatment group.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Blinding implementation details:

In order to reduce potential bias in patient evaluation and data analysis, all patients, site personnel and Sponsor personnel were blinded to treatment assignment, with the exception of a small Sponsor subteam who received unblinded group means of DAS28-4(CRP) efficacy results and the clinical pharmacology team.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Placebo tablets were identical in appearance to both the 10 mg and 20 mg ARRY-438162 tablets.

Patients were randomized in a 1:1:1:1 fashion to ARRY-438162 10 mg bid, 40 mg qd or 20 mg bid, or placebo.

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

Dosage and administration details:

Placebo tablets identical in appearance to both the 10 mg and 20 mg ARRY-438162 tablets.

Arm title	ARRY-438162: 10 mg bid

Arm description:

Patients were randomized in a 1:1:1:1 fashion to ARRY-438162 10 mg bid, 40 mg qd or 20 mg bid, or placebo.

Arm type	Experimental
Investigational medicinal product name	ARRY-438162
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ARRY-438162 was supplied as yellow, round, convex film-coated tablets in strengths of 10 mg and 20 mg.

Arm title	ARRY-438162: 40 mg qd

Arm description:

Patients were randomized in a 1:1:1:1 fashion to ARRY-438162 10 mg bid, 40 mg qd or 20 mg bid, or placebo.

Arm type	Experimental
Investigational medicinal product name	ARRY-438162
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ARRY-438162 was supplied as yellow, round, convex film-coated tablets in strengths of 10 mg and 20 mg.

Arm title	ARRY-438162: 20 mg bid

Arm description:

Patients were randomized in a 1:1:1:1 fashion to ARRY-438162 10 mg bid, 40 mg qd or 20 mg bid, or placebo.

Arm type	Experimental
Investigational medicinal product name	ARRY-438162
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

ARRY-438162 was supplied as yellow, round, convex film-coated tablets in strengths of 10 mg and 20 mg.

Number of subjects in period 1	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd
Started	51	50	50
Completed	46	41	36
Not completed	5	9	14
Adverse event, serious fatal	1	-	-
Consent withdrawn by subject	2	4	3
Adverse event, non-fatal	-	3	10
Unknown	1	1	-
Lost to follow-up	1	1	1

Number of subjects in period 1	ARRY-438162: 20 mg bid
Started	50
Completed	39
Not completed	11
Adverse event, serious fatal	-
Consent withdrawn by subject	3
Adverse event, non-fatal	8
Unknown	-

Lost to follow-up	-

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Placebo tablets were identical in appearance to both the 10 mg and 20 mg ARRY-438162 tablets. Patients were randomized in a 1:1:1:1 fashion to ARRY-438162 10 mg bid, 40 mg qd or 20 mg bid, or placebo.	
Reporting group title	ARRY-438162: 10 mg bid
Reporting group description:	
Patients were randomized in a 1:1:1:1 fashion to ARRY-438162 10 mg bid, 40 mg qd or 20 mg bid, or placebo.	
Reporting group title	ARRY-438162: 40 mg qd
Reporting group description:	
Patients were randomized in a 1:1:1:1 fashion to ARRY-438162 10 mg bid, 40 mg qd or 20 mg bid, or placebo.	
Reporting group title	ARRY-438162: 20 mg bid
Reporting group description:	
Patients were randomized in a 1:1:1:1 fashion to ARRY-438162 10 mg bid, 40 mg qd or 20 mg bid, or placebo.	

Reporting group values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd
Number of subjects	51	50	50
Age Categorical Units: participants			
<=18 years	0	0	0
Between 18 and 65 years	43	45	41
>=65 years	8	5	9
Age Continuous Units: years			
arithmetic mean	52	51.6	54.8
standard deviation	± 12.67	± 11.98	± 11.88
Gender, Male/Female Units: participants			
Female	43	42	43
Male	8	8	7
Race/Ethnicity, Customized Units: Subjects			
Hispanic Or Latino	24	21	23
Not Hispanic Or Latino	27	29	27
Smoking Status Units: Subjects			
Current Smoker	6	10	9
Never Smoked	38	39	36
Past Smoker	7	1	5
Weight Units: kilogram			
arithmetic mean	74.1	68.2	72.1
standard deviation	± 18.26	± 14.17	± 17.95

Height			
Units: centimeters			
arithmetic mean	160.2	159.5	158.6
standard deviation	± 8.63	± 8.11	± 9.22

Reporting group values	ARRY-438162: 20 mg bid	Total	
Number of subjects	50	201	
Age Categorical			
Units: participants			
<=18 years	0	0	
Between 18 and 65 years	45	174	
>=65 years	5	27	
Age Continuous			
Units: years			
arithmetic mean	51.4		
standard deviation	± 11.74	-	
Gender, Male/Female			
Units: participants			
Female	44	172	
Male	6	29	
Race/Ethnicity, Customized			
Units: Subjects			
Hispanic Or Latino	24	92	
Not Hispanic Or Latino	26	109	
Smoking Status			
Units: Subjects			
Current Smoker	12	37	
Never Smoked	36	149	
Past Smoker	2	15	
Weight			
Units: kilogram			
arithmetic mean	67.2		
standard deviation	± 13.86	-	
Height			
Units: centimeters			
arithmetic mean	158		
standard deviation	± 7.44	-	

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Placebo tablets were identical in appearance to both the 10 mg and 20 mg ARRY-438162 tablets. Patients were randomized in a 1:1:1:1 fashion to ARRY-438162 10 mg bid, 40 mg qd or 20 mg bid, or placebo.	
Reporting group title	ARRY-438162: 10 mg bid
Reporting group description:	
Patients were randomized in a 1:1:1:1 fashion to ARRY-438162 10 mg bid, 40 mg qd or 20 mg bid, or placebo.	
Reporting group title	ARRY-438162: 40 mg qd
Reporting group description:	
Patients were randomized in a 1:1:1:1 fashion to ARRY-438162 10 mg bid, 40 mg qd or 20 mg bid, or placebo.	
Reporting group title	ARRY-438162: 20 mg bid
Reporting group description:	
Patients were randomized in a 1:1:1:1 fashion to ARRY-438162 10 mg bid, 40 mg qd or 20 mg bid, or placebo.	

Primary: American College of Rheumatology 20% (ACR20) response rate at Week 12

End point title	American College of Rheumatology 20% (ACR20) response rate at Week 12[1]
End point description:	
The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis. The ACR 20 has a positive outcome if 20% improvement in tender or swollen joint counts were achieved as well as a 20% improvement in at least three of the other five criteria.	
End point type	Primary
End point timeframe:	
Week 12	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Not applicable.

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	51	50	50	50
Units: units on a scale				
number (confidence interval 95%)	45.1 (31.1 to 59.7)	58 (43.2 to 71.8)	60 (45.2 to 73.6)	54 (39.3 to 68.2)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology 20% (ACR20) Response Rate at Week 1

End point title	American College of Rheumatology 20% (ACR20) Response Rate at Week 1

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The ACR 20 has a positive outcome if 20% improvement in tender or swollen joint counts were achieved as well as a 20% improvement in at least three of the other five criteria.

End point type	Secondary

End point timeframe:

Week 1

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
number (confidence interval 95%)	12.2 (4.6 to 24.8)	20.8 (10.5 to 35)	32.7 (19.9 to 47.5)	46 (31.8 to 60.7)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology 20% (ACR20) Response Rate at Week 2

End point title	American College of Rheumatology 20% (ACR20) Response Rate at Week 2

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The ACR 20 has a positive outcome if 20% improvement in tender or swollen joint counts were achieved as well as a 20% improvement in at least three of the other five criteria.

End point type	Secondary

End point timeframe:

Week 2

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
number (confidence interval 95%)	18.4 (8.8 to 32)	31.3 (18.7 to 46.3)	32.7 (19.9 to 47.5)	50 (35.5 to 64.5)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology 20% (ACR20) Response Rate at Week 4

End point title	American College of Rheumatology 20% (ACR20) Response Rate at Week 4

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The ACR 20 has a positive outcome if 20% improvement in tender or swollen joint counts were achieved as well as a 20% improvement in at least three of the other five criteria.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
number (confidence interval 95%)	44.9 (30.7 to 59.8)	54.2 (39.2 to 68.6)	44.9 (30.7 to 59.8)	58 (43.2 to 71.8)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology 20% (ACR20) Response Rate at Week 8

End point title	American College of Rheumatology 20% (ACR20) Response Rate at Week 8

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The ACR 20 has a positive outcome if 20% improvement in tender or swollen joint counts were achieved as well as a 20% improvement in at least three of the other five criteria.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
number (confidence interval 95%)	49 (34.4 to 63.7)	56.3 (41.2 to 70.5)	53.1 (38.3 to 67.5)	48 (33.7 to 62.6)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology 20% (ACR20) Response Rate at Week 16 (Follow-up)

End point title	American College of Rheumatology 20% (ACR20) Response Rate at Week 16 (Follow-up)

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The ACR 20 has a positive outcome if 20% improvement in tender or swollen joint counts were achieved as well as a 20% improvement in at least three of the other five criteria.

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
number (confidence interval 95%)	40.8 (27 to 55.8)	52.1 (37.2 to 66.7)	49 (34.4 to 63.7)	46 (31.8 to 60.7)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology 50% (ACR50) Response Rate at Week 1

End point title	American College of Rheumatology 50% (ACR50) Response Rate at Week 1

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The ACR 50 has a positive outcome if 50% improvement in tender or swollen joint counts were achieved as well as a 50% improvement in at least three of the other five criteria.

End point type	Secondary

End point timeframe:

Week 1

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
number (confidence interval 95%)	2 (0.1 to 10.9)	6.3 (1.3 to 17.2)	2 (0.1 to 10.9)	4 (0.5 to 13.7)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology 50% (ACR50) Response Rate at Week 2

End point title	American College of Rheumatology 50% (ACR50) Response Rate at Week 2

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The ACR 50 has a positive outcome if 50% improvement in tender or swollen joint counts were achieved as well as a 50% improvement in at least three of the other five criteria.

End point type	Secondary

End point timeframe:

Week 2

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
number (confidence interval 95%)	6.1 (1.3 to 16.9)	8.3 (2.3 to 20)	10.2 (3.4 to 22.2)	16 (7.2 to 29.1)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology 50% (ACR50) Response Rate at Week 4

End point title	American College of Rheumatology 50% (ACR50) Response Rate at Week 4

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The ACR 50 has a positive outcome if 50% improvement in tender or swollen joint counts were achieved as well as a 50% improvement in at least three of the other five criteria.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
number (confidence interval 95%)	10.2 (3.4 to 22.2)	8.3 (2.3 to 20)	12.2 (4.6 to 24.8)	16 (7.2 to 29.1)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology 50% (ACR50) Response Rate at Week 8

End point title	American College of Rheumatology 50% (ACR50) Response Rate at Week 8

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The ACR 50 has a positive outcome if 50% improvement in tender or swollen joint counts were achieved as well as a 50% improvement in at least three of the other five criteria.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
number (confidence interval 95%)	16.3 (7.3 to 29.7)	27.1 (15.3 to 41.8)	16.3 (7.3 to 29.7)	22 (11.5 to 36)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology 50% (ACR50) Response Rate at Week 12

End point title	American College of Rheumatology 50% (ACR50) Response Rate at Week 12

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The ACR 50 has a positive outcome if 50% improvement in tender or swollen joint counts were achieved as well as a 50% improvement in at least three of the other five criteria.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
number (confidence interval 95%)	24.5 (13.3 to 38.9)	25 (13.6 to 39.6)	22.4 (11.8 to 36.6)	22 (11.5 to 36)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology 50% (ACR50) Response Rate at Week 16 (Follow-up)

End point title	American College of Rheumatology 50% (ACR50) Response Rate at Week 16 (Follow-up)

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The ACR 50 has a positive outcome if 50% improvement in tender or swollen joint counts were achieved as well as a 50% improvement in at least three of the other five criteria.

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
number (confidence interval 95%)	16.3 (7.3 to 29.7)	27.1 (15.3 to 41.8)	30.6 (18.3 to 45.4)	14 (5.8 to 26.7)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology 70% (ACR70) Response Rate at Week 1

End point title	American College of Rheumatology 70% (ACR70) Response Rate at Week 1

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The ACR 70 has a positive outcome if 70% improvement in tender or swollen joint counts were achieved as well as a 70% improvement in at least three of the other five criteria.

End point type	Secondary

End point timeframe:

Week 1

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
number (confidence interval 95%)	0 (0 to 7.3)	2.1 (0.1 to 11.1)	0 (0 to 7.3)	2 (0.1 to 10.6)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology 70% (ACR70) Response Rate at Week 2

End point title	American College of Rheumatology 70% (ACR70) Response Rate at Week 2

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The ACR 70 has a positive outcome if 70% improvement in tender or swollen joint counts were achieved as well as a 70% improvement in at least three of the other five criteria.

End point type	Secondary

End point timeframe:

Week 2

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
number (confidence interval 95%)	2 (0.1 to 10.9)	4.2 (0.5 to 14.3)	0 (0 to 7.3)	2 (0.1 to 10.6)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology 70% (ACR70) Response Rate at Week 4

End point title	American College of Rheumatology 70% (ACR70) Response Rate at Week 4

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The ACR 70 has a positive outcome if 70% improvement in tender or swollen joint counts were achieved as well as a 70% improvement in at least three of the other five criteria.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
number (confidence interval 95%)	0 (0 to 7.3)	4.2 (0.5 to 14.3)	2 (0.1 to 10.9)	2 (0.1 to 10.6)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology 70% (ACR70) Response Rate at Week 8

End point title	American College of Rheumatology 70% (ACR70) Response Rate at Week 8

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The ACR 70 has a positive outcome if 70% improvement in tender or swollen joint counts were achieved as well as a 70% improvement in at least three of the other five criteria.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
number (confidence interval 95%)	4.1 (0.5 to 14)	4.2 (0.5 to 14.3)	4.1 (0.5 to 14)	4 (0.5 to 13.7)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology 70% (ACR70) Response Rate at Week 12

End point title	American College of Rheumatology 70% (ACR70) Response Rate at Week 12

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The ACR 70 has a positive outcome if 70% improvement in tender or swollen joint counts were achieved as well as a 70% improvement in at least three of the other five criteria.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
number (confidence interval 95%)	8.2 (2.3 to 19.6)	12.5 (4.7 to 25.2)	8.2 (2.3 to 19.6)	6 (1.3 to 16.5)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology 70% (ACR70) Response Rate at Week 16 (Follow-up)

End point title	American College of Rheumatology 70% (ACR70) Response Rate at Week 16 (Follow-up)

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The ACR 70 has a positive outcome if 70% improvement in tender or swollen joint counts were achieved as well as a 70% improvement in at least three of the other five criteria.

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
number (confidence interval 95%)	6.1 (1.3 to 16.9)	6.3 (1.3 to 17.2)	6.1 (1.3 to 16.9)	10 (3.3 to 21.8)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology (ACR) Response Criteria - Tender Joint Count (28)

End point title	American College of Rheumatology (ACR) Response Criteria - Tender Joint Count (28)

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

Tender joint count is calculated based on the tenderness response of 28 joints. Possible values ranged from 0 to 28. A lower score indicated less joint tenderness.

End point type	Secondary

End point timeframe:

Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	16.8 (± 6.44)	14.8 (± 5.49)	15 (± 5.98)	17 (± 5.95)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology (ACR) Response Criteria - Tender Joint Count (28)

End point title	American College of Rheumatology (ACR) Response Criteria - Tender Joint Count (28)

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

Tender joint count is calculated based on the tenderness response of 28 joints. Possible values ranged from 0 to 28. A lower score indicated less joint tenderness.

End point type	Secondary

End point timeframe:

Week 1

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	14.9 (± 6.81)	11.6 (± 6.24)	11.6 (± 6.46)	11.1 (± 5.84)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology (ACR) Response Criteria - Tender Joint Count (28)

End point title	American College of Rheumatology (ACR) Response Criteria - Tender Joint Count (28)

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

Tender joint count is calculated based on the tenderness response of 28 joints. Possible values ranged from 0 to 28. A lower score indicated less joint tenderness.

End point type	Secondary

End point timeframe:

Week 2

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	12.3 (± 6.5)	10.2 (± 6.49)	11.4 (± 6.31)	10 (± 6)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology (ACR) Response Criteria - Tender Joint Count (28)

End point title	American College of Rheumatology (ACR) Response Criteria - Tender Joint Count (28)

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

Tender joint count is calculated based on the tenderness response of 28 joints. Possible values ranged from 0 to 28. A lower score indicated less joint tenderness.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	11.6 (± 7.46)	9 (± 6.31)	9.6 (± 6.84)	8.9 (± 6.02)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology (ACR) Response Criteria - Tender Joint Count (28)

End point title	American College of Rheumatology (ACR) Response Criteria - Tender Joint Count (28)

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

Tender joint count is calculated based on the tenderness response of 28 joints. Possible values ranged from 0 to 28. A lower score indicated less joint tenderness.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	9.9 (± 7.21)	8.1 (± 7.04)	8.3 (± 6.27)	7.5 (± 5.5)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology (ACR) Response Criteria - Tender Joint Count (28)

End point title	American College of Rheumatology (ACR) Response Criteria - Tender Joint Count (28)

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

Tender joint count is calculated based on the tenderness response of 28 joints. Possible values ranged from 0 to 28. A lower score indicated less joint tenderness.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	9.4 (± 7.09)	7.1 (± 7.05)	7.8 (± 7.5)	7.8 (± 6.57)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology (ACR) Response Criteria - Tender Joint Count (28)

End point title	American College of Rheumatology (ACR) Response Criteria - Tender Joint Count (28)

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

Tender joint count is calculated based on the tenderness response of 28 joints. Possible values ranged from 0 to 28. A lower score indicated less joint tenderness.

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	9.1 (± 7.13)	7.4 (± 7.15)	9.2 (± 7.37)	8.9 (± 6.97)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology (ACR) Response Criteria - Swollen Joint Count (28)

End point title	American College of Rheumatology (ACR) Response Criteria - Swollen Joint Count (28)

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The swollen joint count was calculated based on the swelling response of 28 joints. Possible values ranged from 0 to 28. A lower score indicated less joint swelling.

End point type	Secondary

End point timeframe:

Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	12.7 (± 4.45)	11.4 (± 4.1)	12.3 (± 4.96)	13 (± 5.31)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology (ACR) Response Criteria - Swollen Joint Count (28)

End point title	American College of Rheumatology (ACR) Response Criteria - Swollen Joint Count (28)

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The swollen joint count was calculated based on the swelling response of 28 joints. Possible values ranged from 0 to 28. A lower score indicated less joint swelling.

End point type	Secondary

End point timeframe:

Week 1

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	11.3 (± 5.72)	8 (± 4.65)	9.6 (± 4.8)	9.1 (± 4.96)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology (ACR) Response Criteria - Swollen Joint Count (28)

End point title	American College of Rheumatology (ACR) Response Criteria - Swollen Joint Count (28)

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The swollen joint count was calculated based on the swelling response of 28 joints. Possible values ranged from 0 to 28. A lower score indicated less joint swelling.

End point type	Secondary

End point timeframe:

Week 2

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	9.4 (± 5.45)	6.9 (± 4.98)	8.7 (± 4.58)	7.3 (± 5.76)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology (ACR) Response Criteria - Swollen Joint Count (28)

End point title	American College of Rheumatology (ACR) Response Criteria - Swollen Joint Count (28)

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The swollen joint count was calculated based on the swelling response of 28 joints. Possible values ranged from 0 to 28. A lower score indicated less joint swelling.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	7.9 (± 5.14)	5.8 (± 4)	7 (± 4.7)	7.1 (± 6.03)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology (ACR) Response Criteria - Swollen Joint Count (28)

End point title	American College of Rheumatology (ACR) Response Criteria - Swollen Joint Count (28)

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The swollen joint count was calculated based on the swelling response of 28 joints. Possible values ranged from 0 to 28. A lower score indicated less joint swelling.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	6.7 (± 5.25)	5.5 (± 4.64)	6.9 (± 5.51)	6.5 (± 5.96)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology (ACR) Response Criteria - Swollen Joint Count (28)

End point title	American College of Rheumatology (ACR) Response Criteria - Swollen Joint Count (28)

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The swollen joint count was calculated based on the swelling response of 28 joints. Possible values ranged from 0 to 28. A lower score indicated less joint swelling.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	6.3 (± 5.67)	5.3 (± 4.86)	6.3 (± 5.54)	6.3 (± 5.92)

Statistical analyses

No statistical analyses for this end point

Secondary: American College of Rheumatology (ACR) Response Criteria - Swollen Joint Count (28)

End point title	American College of Rheumatology (ACR) Response Criteria - Swollen Joint Count (28)

End point description:

The ACR (American College of Rheumatology) Criteria is a standard criteria to measure the effectiveness of various arthritis medications or treatments in clinical trials for Rheumatoid Arthritis.

The swollen joint count was calculated based on the swelling response of 28 joints. Possible values ranged from 0 to 28. A lower score indicated less joint swelling.

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	6.5 (± 5.69)	4.8 (± 4.63)	6.9 (± 5.72)	6.5 (± 5.96)

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's Assessment of Arthritis Pain - Visual Analog Scale (VAS)

End point title	Patient's Assessment of Arthritis Pain - Visual Analog Scale (VAS)

End point description:

The Patient's Assessment of Pain utilized a 0 to 100 mm visual analog scale, 0 being no pain and 100

being most severe pain.

End point type	Secondary

End point timeframe:

Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	68.7 (± 18.94)	61.9 (± 20.32)	62.4 (± 21.42)	63 (± 18.95)

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's Assessment of Arthritis Pain - Visual Analog Scale (VAS)

End point title	Patient's Assessment of Arthritis Pain - Visual Analog Scale (VAS)

End point description:

The Patient’s Assessment of Pain utilized a 0 to 100 mm visual analog scale, 0 being no pain and 100 being most severe pain.

End point type	Secondary

End point timeframe:

Week 1

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	61.5 (± 25.16)	47.9 (± 22.94)	48.4 (± 22.53)	42.6 (± 20.62)

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's Assessment of Arthritis Pain - Visual Analog Scale (VAS)

End point title	Patient's Assessment of Arthritis Pain - Visual Analog Scale (VAS)

End point description:

The Patient’s Assessment of Pain utilized a 0 to 100 mm visual analog scale, 0 being no pain and 100 being most severe pain.

End point type	Secondary

End point timeframe:

Week 2

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	56.5 (± 23.89)	46.4 (± 22.61)	47.7 (± 25.2)	39.6 (± 22.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's Assessment of Arthritis Pain - Visual Analog Scale (VAS)

End point title	Patient's Assessment of Arthritis Pain - Visual Analog Scale (VAS)

End point description:

The Patient’s Assessment of Pain utilized a 0 to 100 mm visual analog scale, 0 being no pain and 100 being most severe pain.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	50.3 (± 23.78)	44.5 (± 25.23)	44.8 (± 24.48)	39 (± 19.75)

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's Assessment of Arthritis Pain - Visual Analog Scale (VAS)

End point title	Patient's Assessment of Arthritis Pain - Visual Analog Scale (VAS)

End point description:

The Patient’s Assessment of Pain utilized a 0 to 100 mm visual analog scale, 0 being no pain and 100 being most severe pain.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	49.7 (± 26.53)	46.1 (± 24.97)	46.4 (± 25.42)	41.5 (± 23.39)

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's Assessment of Arthritis Pain - Visual Analog Scale (VAS)

End point title	Patient's Assessment of Arthritis Pain - Visual Analog Scale (VAS)

End point description:

The Patient’s Assessment of Pain utilized a 0 to 100 mm visual analog scale, 0 being no pain and 100 being most severe pain.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	45.9 (± 28.15)	43.9 (± 27.39)	43.8 (± 26.93)	42.3 (± 21.46)

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's Assessment of Arthritis Pain - Visual Analog Scale (VAS)

End point title	Patient's Assessment of Arthritis Pain - Visual Analog Scale (VAS)

End point description:

The Patient’s Assessment of Pain utilized a 0 to 100 mm visual analog scale, 0 being no pain and 100 being most severe pain.

End point type	Secondary

End point timeframe:
Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	50.7 (± 27.93)	47.1 (± 26.32)	48.7 (± 27.09)	48.5 (± 23.93)

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point title	Patient's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point description:

The Patient's Global Assessment of Arthritis was an evaluation based on the patient's disease signs, functional capacity and physical examination, and was independent of the Physician's Global Assessment of Arthritis. The patient self-assessed how the arthritis affected their lives at the time of the visit using the visual analog scale (VAS).

Patients answered the following: "Considering all the ways in which illness and health conditions may affect you at this time, please make a mark below to show how you are doing." The patient's response was recorded using the 100 mm visual analog scale between 0 (Very Well) and 100 (Very Poorly).

End point type	Secondary

End point timeframe:
Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	65.2 (± 20.59)	60.1 (± 20.8)	63.4 (± 19.25)	55.4 (± 20.34)

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point title	Patient's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point description:

The Patient’s Global Assessment of Arthritis was an evaluation based on the patient’s disease signs, functional capacity and physical examination, and was independent of the Physician’s Global Assessment of Arthritis. The patient self-assessed how the arthritis affected their lives at the time of the visit using the visual analog scale (VAS).

Patients answered the following: “Considering all the ways in which illness and health conditions may affect you at this time, please make a mark below to show how you are doing.” The patient’s response was recorded using the 100 mm visual analog scale between 0 (Very Well) and 100 (Very Poorly).

End point type	Secondary

End point timeframe:

Week 1

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	57.2 (± 24.52)	45.8 (± 22.65)	48.3 (± 22.82)	42.3 (± 20.66)

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point title	Patient's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point description:

The Patient’s Global Assessment of Arthritis was an evaluation based on the patient’s disease signs, functional capacity and physical examination, and was independent of the Physician’s Global Assessment of Arthritis. The patient self-assessed how the arthritis affected their lives at the time of the visit using the visual analog scale (VAS).

Patients answered the following: “Considering all the ways in which illness and health conditions may affect you at this time, please make a mark below to show how you are doing.” The patient’s response was recorded using the 100 mm visual analog scale between 0 (Very Well) and 100 (Very Poorly).

End point type	Secondary

End point timeframe:

Week 2

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	57.6 (± 21.74)	46.3 (± 23.62)	49.4 (± 22.61)	40.3 (± 22.33)

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point title	Patient's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point description:

The Patient’s Global Assessment of Arthritis was an evaluation based on the patient’s disease signs, functional capacity and physical examination, and was independent of the Physician’s Global Assessment of Arthritis. The patient self-assessed how the arthritis affected their lives at the time of the visit using the visual analog scale (VAS).

Patients answered the following: “Considering all the ways in which illness and health conditions may affect you at this time, please make a mark below to show how you are doing.” The patient’s response was recorded using the 100 mm visual analog scale between 0 (Very Well) and 100 (Very Poorly).

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	50.5 (± 23.96)	43.5 (± 24.57)	46.7 (± 23.7)	40 (± 20.55)

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point title	Patient's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point description:

The Patient’s Global Assessment of Arthritis was an evaluation based on the patient’s disease signs, functional capacity and physical examination, and was independent of the Physician’s Global Assessment of Arthritis. The patient self-assessed how the arthritis affected their lives at the time of the visit using the visual analog scale (VAS).

Patients answered the following: “Considering all the ways in which illness and health conditions may affect you at this time, please make a mark below to show how you are doing.” The patient’s response was recorded using the 100 mm visual analog scale between 0 (Very Well) and 100 (Very Poorly).

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	48.7 (± 26.34)	42.9 (± 24.69)	45.5 (± 22.95)	41.8 (± 21.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point title	Patient's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point description:

The Patient’s Global Assessment of Arthritis was an evaluation based on the patient’s disease signs, functional capacity and physical examination, and was independent of the Physician’s Global Assessment of Arthritis. The patient self-assessed how the arthritis affected their lives at the time of the visit using the visual analog scale (VAS).

Patients answered the following: “Considering all the ways in which illness and health conditions may affect you at this time, please make a mark below to show how you are doing.” The patient’s response was recorded using the 100 mm visual analog scale between 0 (Very Well) and 100 (Very Poorly).

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	45.5 (± 26.71)	40.6 (± 23.24)	43.4 (± 24.82)	41.1 (± 19.75)

Statistical analyses

No statistical analyses for this end point

Secondary: Patient's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point title	Patient's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point description:

The Patient’s Global Assessment of Arthritis was an evaluation based on the patient’s disease signs, functional capacity and physical examination, and was independent of the Physician’s Global Assessment of Arthritis. The patient self-assessed how the arthritis affected their lives at the time of the visit using the visual analog scale (VAS).

Patients answered the following: “Considering all the ways in which illness and health conditions may affect you at this time, please make a mark below to show how you are doing.” The patient’s response was recorded using the 100 mm visual analog scale between 0 (Very Well) and 100 (Very Poorly).

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	46.9 (± 26.69)	42.6 (± 22.99)	47.5 (± 27.18)	44.8 (± 21.95)

Statistical analyses

No statistical analyses for this end point

Secondary: Physician's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point title	Physician's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point description:

The Physician's Global Assessment of Arthritis was an evaluation based on the patient's disease signs, functional capacity and physical examination, and was independent of the Patient's Global Assessment of Arthritis. The Investigator assessed how the overall arthritis appeared at the time of the visit using the visual analog scale (VAS).

The physician's response was recorded using the 100 mm visual analog scale between 0 (Very Good) and 100 (Very Bad).

End point type	Secondary

End point timeframe:

Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	61.2 (± 16.71)	66 (± 13.8)	61 (± 15.23)	59.7 (± 13.26)

Statistical analyses

No statistical analyses for this end point

Secondary: Physician's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point title	Physician's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point description:

The Physician’s Global Assessment of Arthritis was an evaluation based on the patient’s disease signs, functional capacity and physical examination, and was independent of the Patient’s Global Assessment of Arthritis. The Investigator assessed how the overall arthritis appeared at the time of the visit using the visual analog scale (VAS).

The physician’s response was recorded using the 100 mm visual analog scale between 0 (Very Good) and 100 (Very Bad).

End point type	Secondary

End point timeframe:

Week 1

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	53.7 (± 17.8)	47.7 (± 19.55)	46.8 (± 18.21)	41.1 (± 17.14)

Statistical analyses

No statistical analyses for this end point

Secondary: Physician’s Global Assessment of Arthritis - Visual Analog Score (VAS)

End point title	Physician’s Global Assessment of Arthritis - Visual Analog Score (VAS)

End point description:

The Physician’s Global Assessment of Arthritis was an evaluation based on the patient’s disease signs, functional capacity and physical examination, and was independent of the Patient’s Global Assessment of Arthritis. The Investigator assessed how the overall arthritis appeared at the time of the visit using the visual analog scale (VAS).

The physician’s response was recorded using the 100 mm visual analog scale between 0 (Very Good) and 100 (Very Bad).

End point type	Secondary

End point timeframe:

Week 2

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	47.9 (± 18.61)	41.8 (± 18.67)	43.9 (± 19.45)	35.3 (± 18.27)

Statistical analyses

No statistical analyses for this end point

Secondary: Physician’s Global Assessment of Arthritis - Visual Analog Score (VAS)

End point title	Physician’s Global Assessment of Arthritis - Visual Analog Score (VAS)

End point description:

The Physician’s Global Assessment of Arthritis was an evaluation based on the patient’s disease signs, functional capacity and physical examination, and was independent of the Patient’s Global Assessment of Arthritis. The Investigator assessed how the overall arthritis appeared at the time of the visit using the visual analog scale (VAS).

The physician’s response was recorded using the 100 mm visual analog scale between 0 (Very Good) and 100 (Very Bad).

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	42 (± 19.83)	39.9 (± 21.55)	38.8 (± 18.4)	34.7 (± 19.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Physician’s Global Assessment of Arthritis - Visual Analog Score (VAS)

End point title	Physician’s Global Assessment of Arthritis - Visual Analog Score (VAS)

End point description:

The Physician’s Global Assessment of Arthritis was an evaluation based on the patient’s disease signs, functional capacity and physical examination, and was independent of the Patient’s Global Assessment

of Arthritis. The Investigator assessed how the overall arthritis appeared at the time of the visit using the visual analog scale (VAS).

The physician's response was recorded using the 100 mm visual analog scale between 0 (Very Good) and 100 (Very Bad).

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	39.5 (± 20.96)	37 (± 21.21)	36.8 (± 18.88)	32.7 (± 22.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Physician's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point title	Physician's Global Assessment of Arthritis - Visual Analog Score (VAS)

End point description:

The Physician's Global Assessment of Arthritis was an evaluation based on the patient's disease signs, functional capacity and physical examination, and was independent of the Patient's Global Assessment of Arthritis. The Investigator assessed how the overall arthritis appeared at the time of the visit using the visual analog scale (VAS).

The physician's response was recorded using the 100 mm visual analog scale between 0 (Very Good) and 100 (Very Bad).

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	35.8 (± 21.96)	34.9 (± 22.19)	35.7 (± 21.06)	31.2 (± 21.64)

Statistical analyses

No statistical analyses for this end point

Secondary: Physician’s Global Assessment of Arthritis - Visual Analog Score (VAS)

End point title	Physician’s Global Assessment of Arthritis - Visual Analog Score (VAS)

End point description:

The Physician’s Global Assessment of Arthritis was an evaluation based on the patient’s disease signs, functional capacity and physical examination, and was independent of the Patient’s Global Assessment of Arthritis. The Investigator assessed how the overall arthritis appeared at the time of the visit using the visual analog scale (VAS).

The physician’s response was recorded using the 100 mm visual analog scale between 0 (Very Good) and 100 (Very Bad).

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	36.7 (± 20.86)	33.2 (± 19.22)	40.7 (± 21.92)	34.6 (± 20.37)

Statistical analyses

No statistical analyses for this end point

Secondary: Health Assessment Questionnaire – Disability Index (HAQ-DI)

End point title	Health Assessment Questionnaire – Disability Index (HAQ-DI)

End point description:

The HAQ-DI contains a list of items that assessed the degree of difficulty experienced in 8 categories of daily living activities (included in 20 questions) over the past week: Dressing and grooming, arising, eating, walking, hygiene, reach, grip and other activities. Each activity category consists of 2 or 3 items. For each question in the HAQ-DI, the level of difficulty was scored from 0 to 3 with 0 equal to "without difficulty," 1 equal to "with some difficulty," 2 equal to "with much difficulty" and 3 equal to "unable to do." Any activity that required assistance from another individual or required the use of an assistive device adjusted to a minimum score of 2 to represent a more limited functional status.

End point type	Secondary

End point timeframe:

Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	1.6 (± 0.59)	1.5 (± 0.52)	1.5 (± 0.53)	1.5 (± 0.65)

Statistical analyses

No statistical analyses for this end point

Secondary: Health Assessment Questionnaire – Disability Index (HAQ-DI)

End point title	Health Assessment Questionnaire – Disability Index (HAQ-DI)

End point description:

The HAQ-DI contains a list of items that assessed the degree of difficulty experienced in 8 categories of daily living activities (included in 20 questions) over the past week: Dressing and grooming, arising, eating, walking, hygiene, reach, grip and other activities. Each activity category consists of 2 or 3 items. For each question in the HAQ-DI, the level of difficulty was scored from 0 to 3 with 0 equal to "without difficulty," 1 equal to "with some difficulty," 2 equal to "with much difficulty" and 3 equal to "unable to do." Any activity that required assistance from another individual or required the use of an assistive device adjusted to a minimum score of 2 to represent a more limited functional status.

End point type	Secondary

End point timeframe:

Week 1

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	1.6 (± 0.66)	1.3 (± 0.58)	1.3 (± 0.63)	1.2 (± 0.68)

Statistical analyses

No statistical analyses for this end point

Secondary: Health Assessment Questionnaire – Disability Index (HAQ-DI)

End point title	Health Assessment Questionnaire – Disability Index (HAQ-DI)

End point description:

The HAQ-DI contains a list of items that assessed the degree of difficulty experienced in 8 categories of daily living activities (included in 20 questions) over the past week: Dressing and grooming, arising, eating, walking, hygiene, reach, grip and other activities. Each activity category consists of 2 or 3 items. For each question in the HAQ-DI, the level of difficulty was scored from 0 to 3 with 0 equal to "without difficulty," 1 equal to "with some difficulty," 2 equal to "with much difficulty" and 3 equal to "unable to do." Any activity that required assistance from another individual or required the use of an assistive device adjusted to a minimum score of 2 to represent a more limited functional status.

End point type	Secondary

End point timeframe:

Week 2

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	1.5 (± 0.59)	1.3 (± 0.59)	1.3 (± 0.62)	1 (± 0.62)

Statistical analyses

No statistical analyses for this end point

Secondary: Health Assessment Questionnaire – Disability Index (HAQ-DI)

End point title	Health Assessment Questionnaire – Disability Index (HAQ-DI)

End point description:

The HAQ-DI contains a list of items that assessed the degree of difficulty experienced in 8 categories of daily living activities (included in 20 questions) over the past week: Dressing and grooming, arising, eating, walking, hygiene, reach, grip and other activities. Each activity category consists of 2 or 3 items. For each question in the HAQ-DI, the level of difficulty was scored from 0 to 3 with 0 equal to "without difficulty," 1 equal to "with some difficulty," 2 equal to "with much difficulty" and 3 equal to "unable to do." Any activity that required assistance from another individual or required the use of an assistive device adjusted to a minimum score of 2 to represent a more limited functional status.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	1.4 (± 0.63)	1.3 (± 0.68)	1.2 (± 0.63)	1.1 (± 0.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Health Assessment Questionnaire – Disability Index (HAQ-DI)

End point title	Health Assessment Questionnaire – Disability Index (HAQ-DI)

End point description:

The HAQ-DI contains a list of items that assessed the degree of difficulty experienced in 8 categories of daily living activities (included in 20 questions) over the past week: Dressing and grooming, arising,

eating, walking, hygiene, reach, grip and other activities. Each activity category consists of 2 or 3 items. For each question in the HAQ-DI, the level of difficulty was scored from 0 to 3 with 0 equal to "without difficulty," 1 equal to "with some difficulty," 2 equal to "with much difficulty" and 3 equal to "unable to do." Any activity that required assistance from another individual or required the use of an assistive device adjusted to a minimum score of 2 to represent a more limited functional status.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	1.4 (± 0.7)	1.2 (± 0.72)	1.2 (± 0.62)	1.1 (± 0.66)

Statistical analyses

No statistical analyses for this end point

Secondary: Health Assessment Questionnaire – Disability Index (HAQ-DI)

End point title	Health Assessment Questionnaire – Disability Index (HAQ-DI)

End point description:

The HAQ-DI contains a list of items that assessed the degree of difficulty experienced in 8 categories of daily living activities (included in 20 questions) over the past week: Dressing and grooming, arising, eating, walking, hygiene, reach, grip and other activities. Each activity category consists of 2 or 3 items. For each question in the HAQ-DI, the level of difficulty was scored from 0 to 3 with 0 equal to "without difficulty," 1 equal to "with some difficulty," 2 equal to "with much difficulty" and 3 equal to "unable to do." Any activity that required assistance from another individual or required the use of an assistive device adjusted to a minimum score of 2 to represent a more limited functional status.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	1.3 (± 0.72)	1.1 (± 0.66)	1.1 (± 0.68)	1.1 (± 0.64)

Statistical analyses

No statistical analyses for this end point

Secondary: Health Assessment Questionnaire – Disability Index (HAQ-DI)

End point title	Health Assessment Questionnaire – Disability Index (HAQ-DI)

End point description:

The HAQ-DI contains a list of items that assessed the degree of difficulty experienced in 8 categories of daily living activities (included in 20 questions) over the past week: Dressing and grooming, arising, eating, walking, hygiene, reach, grip and other activities. Each activity category consists of 2 or 3 items. For each question in the HAQ-DI, the level of difficulty was scored from 0 to 3 with 0 equal to "without difficulty," 1 equal to "with some difficulty," 2 equal to "with much difficulty" and 3 equal to "unable to do." Any activity that required assistance from another individual or required the use of an assistive device adjusted to a minimum score of 2 to represent a more limited functional status.

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	1.3 (± 0.76)	1.2 (± 0.7)	1.2 (± 0.64)	1.1 (± 0.62)

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) at Baseline

End point title	C-Reactive Protein (CRP) at Baseline

End point description:

End point type	Secondary

End point timeframe:

Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	1.9 (± 1.42)	1.8 (± 1.18)	2.4 (± 1.86)	2.4 (± 1.95)

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) at Week 1

End point title	C-Reactive Protein (CRP) at Week 1

End point description:

End point type	Secondary

End point timeframe:

Week 1

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	2.2 (± 2.2)	1.9 (± 2.85)	2 (± 2.17)	1.4 (± 1.58)

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) at Week 2

End point title	C-Reactive Protein (CRP) at Week 2

End point description:

End point type	Secondary

End point timeframe:

Week 2

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	1.9 (± 1.7)	1.9 (± 1.7)	2.5 (± 2.36)	2.1 (± 2.07)

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) at Week 4

End point title	C-Reactive Protein (CRP) at Week 4

End point description:

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	1.9 (± 1.55)	2.2 (± 3.18)	2.6 (± 3.02)	2.2 (± 2.25)

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) at Week 8

End point title	C-Reactive Protein (CRP) at Week 8

End point description:

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	2.1 (± 2.24)	2 (± 1.88)	2.6 (± 2.39)	3 (± 3.34)

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) at Week 12

End point title	C-Reactive Protein (CRP) at Week 12

End point description:

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	2.1 (± 2.14)	1.8 (± 1.87)	2.5 (± 2.51)	2.9 (± 2.91)

Statistical analyses

No statistical analyses for this end point

Secondary: C-Reactive Protein (CRP) at Week 16 (Follow-up)

End point title	C-Reactive Protein (CRP) at Week 16 (Follow-up)

End point description:

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	1.9 (± 1.79)	2.3 (± 3.33)	2 (± 1.68)	2.3 (± 2.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Activity Score (DAS) Using C-Reactive Protein (DAS28-4[CRP])

End point title	Disease Activity Score (DAS) Using C-Reactive Protein (DAS28-4[CRP])

End point description:

DAS28-4(CRP) is calculated using the tender joint count, swollen joint count, C-reactive protein, and patient's global assessment of arthritis (VAS in mm from 0 to 100). A lower score indicates less disease activity.

End point type	Secondary

End point timeframe:

Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	6.1 (± 0.77)	5.9 (± 0.61)	6 (± 0.79)	6.1 (± 0.77)

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Activity Score (DAS) using C-Reactive Protein (DAS28-4[CRP])

End point title	Disease Activity Score (DAS) using C-Reactive Protein (DAS28-4[CRP])

End point description:

DAS28-4(CRP) is calculated using the tender joint count, swollen joint count, C-reactive protein, and patient's global assessment of arthritis (VAS in mm from 0 to 100). A lower score indicates less disease activity.

End point type	Secondary

End point timeframe:

Week 1

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	5.8 (± 1.01)	5 (± 1.03)	5.2 (± 1.08)	5 (± 0.97)

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Activity Score (DAS) using C-Reactive Protein (DAS28-4[CRP])

End point title	Disease Activity Score (DAS) using C-Reactive Protein (DAS28-4[CRP])

End point description:

DAS28-4(CRP) is calculated using the tender joint count, swollen joint count, C-reactive protein, and patient's global assessment of arthritis (VAS in mm from 0 to 100). A lower score indicates less disease activity.

End point type	Secondary

End point timeframe:

Week 2

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	5.4 (± 0.94)	4.9 (± 1.17)	5.3 (± 1.06)	4.8 (± 1.14)

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Activity Score (DAS) using C-Reactive Protein (DAS28-4[CRP])

End point title	Disease Activity Score (DAS) using C-Reactive Protein (DAS28-4[CRP])

End point description:

DAS28-4(CRP) is calculated using the tender joint count, swollen joint count, C-reactive protein, and patient's global assessment of arthritis (VAS in mm from 0 to 100). A lower score indicates less disease activity.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	5.2 (± 1.13)	4.7 (± 1.28)	5 (± 1.19)	4.7 (± 1.24)

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Activity Score (DAS) using C-Reactive Protein (DAS28-4[CRP])

End point title	Disease Activity Score (DAS) using C-Reactive Protein (DAS28-4[CRP])

End point description:

DAS28-4(CRP) is calculated using the tender joint count, swollen joint count, C-reactive protein, and patient's global assessment of arthritis (VAS in mm from 0 to 100). A lower score indicates less disease

activity.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	4.9 (± 1.23)	4.6 (± 1.34)	4.8 (± 1.15)	4.6 (± 1.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Activity Score (DAS) using C-Reactive Protein (DAS28-4[CRP])

End point title	Disease Activity Score (DAS) using C-Reactive Protein (DAS28-4[CRP])

End point description:

DAS28-4(CRP) is calculated using the tender joint count, swollen joint count, C-reactive protein, and patient's global assessment of arthritis (VAS in mm from 0 to 100). A lower score indicates less disease activity.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	4.8 (± 1.26)	4.3 (± 1.39)	4.6 (± 1.42)	4.6 (± 1.43)

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Activity Score (DAS) using C-Reactive Protein (DAS28-4[CRP])

End point title	Disease Activity Score (DAS) using C-Reactive Protein (DAS28-4[CRP])

End point description:

DAS28-4(CRP) is calculated using the tender joint count, swollen joint count, C-reactive protein, and

patient’s global assessment of arthritis (VAS in mm from 0 to 100). A lower score indicates less disease activity.

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	4.8 (± 1.2)	4.4 (± 1.27)	4.8 (± 1.42)	4.7 (± 1.42)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Functioning

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Functioning

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	29.8 (± 8.45)	31.4 (± 7.78)	31.6 (± 8.29)	33.8 (± 9.58)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Functioning

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Functioning

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	33.8 (± 9.05)	36 (± 9.1)	34.3 (± 9.73)	38.7 (± 8.74)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Functioning

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Functioning

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	34.2 (± 9.86)	37.2 (± 9.25)	34.9 (± 10.32)	38.2 (± 10.36)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Functioning

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Functioning

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	34.5 (± 11.08)	37.2 (± 9.83)	36.4 (± 10.91)	38.8 (± 9.63)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Functioning

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Functioning

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	35.4 (± 11.1)	36 (± 9.75)	35.5 (± 8.99)	37.8 (± 9.84)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Physical

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Physical

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	30.3 (± 8.47)	32.7 (± 8.07)	32.3 (± 7.68)	32.9 (± 8.49)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Physical

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Physical

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary

measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	34.8 (± 8.2)	37.1 (± 9.69)	37.1 (± 7.89)	38.6 (± 7.88)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Physical

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Physical

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	34.6 (± 9.17)	39.2 (± 9.7)	36.5 (± 8.09)	39.2 (± 9.2)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Physical

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Physical

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	35.1 (± 9.65)	39.7 (± 10.36)	37.9 (± 9.46)	39.3 (± 8.12)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Physical

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Physical

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	36.4 (± 10.45)	38.9 (± 8.5)	36.9 (± 9.48)	38.7 (± 9.21)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Bodily Pain

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Bodily Pain

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	32.5 (± 6.39)	33.1 (± 6.22)	32.4 (± 7.18)	33 (± 6.5)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Bodily Pain

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Bodily Pain

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	37.3 (± 8.49)	38.1 (± 9.22)	38 (± 8.58)	41 (± 9.22)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Bodily Pain

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Bodily Pain

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	37.2 (± 9.05)	39.1 (± 9.73)	38.7 (± 8.27)	40.8 (± 10.11)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Bodily Pain

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Bodily Pain

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary

measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	38.1 (± 10.01)	39.3 (± 9.21)	38.7 (± 9.61)	40.9 (± 9.62)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Bodily Pain

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Bodily Pain

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	37.9 (± 10.62)	38.1 (± 9.89)	37 (± 9.73)	38.1 (± 9.19)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - General Health

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - General Health

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	34.1 (± 6.65)	33.6 (± 8.05)	34 (± 7.85)	36.1 (± 7.44)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - General Health

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - General Health

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	36.4 (± 6)	36.9 (± 9.1)	36.9 (± 9.11)	38.9 (± 9.07)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - General Health

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - General Health

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	36.8 (± 7.96)	37.8 (± 9.1)	36.9 (± 8.21)	39.7 (± 9.29)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - General Health

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - General Health

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	37.8 (± 6.93)	37.1 (± 9.13)	36.7 (± 9.28)	39.2 (± 8.74)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - General Health

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - General Health

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	37.4 (± 8.6)	36.8 (± 9.02)	36.4 (± 8.53)	38.3 (± 9.25)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Vitality

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Vitality

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	40.1 (± 10.1)	41.5 (± 7.79)	41.3 (± 9.17)	44.5 (± 8.3)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Vitality

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Vitality

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	44.3 (± 8.75)	46.3 (± 10.31)	44.7 (± 9.16)	47.3 (± 9.64)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Vitality

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Vitality

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	43.9 (± 9.76)	47.2 (± 11.08)	45.3 (± 10.03)	49 (± 9.3)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Vitality

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Vitality

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	45.5 (± 9.73)	47.8 (± 10.2)	46.3 (± 10.56)	47.5 (± 9.41)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Vitality

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Vitality

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	45.1 (± 10.55)	47.4 (± 11.67)	44.4 (± 9.91)	46.9 (± 9.93)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Social Functioning

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Social Functioning

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	32.7 (± 10.97)	34.1 (± 9.28)	34.7 (± 9.5)	36.7 (± 10.62)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Social Functioning

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Social Functioning

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	36.9 (± 9.74)	39.9 (± 10.07)	38.3 (± 10.04)	38.9 (± 9.71)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Social Functioning

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Social Functioning

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary

measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	37.1 (± 10.41)	40 (± 9.6)	39 (± 10.09)	40.2 (± 9.44)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Social Functioning

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Social Functioning

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	37.3 (± 10.93)	38.9 (± 10.01)	40.2 (± 10.15)	39.6 (± 8.67)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Social Functioning

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Social Functioning

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	37.1 (± 11.97)	39 (± 10.77)	37.2 (± 10.18)	38.8 (± 10.7)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Emotional

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Emotional

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	29.3 (± 12.17)	31.2 (± 11.66)	31.1 (± 9.96)	32.7 (± 13.03)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Emotional

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Emotional

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	34.8 (± 10.88)	36.2 (± 12.69)	34.1 (± 10.32)	34.6 (± 10.96)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Emotional

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Emotional

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	33.3 (± 12.19)	38.3 (± 11.79)	34.5 (± 11.09)	36.5 (± 10.91)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Emotional

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Emotional

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	33.4 (± 12.14)	37.4 (± 12.38)	35 (± 11.46)	36.5 (± 11.17)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Emotional

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Role-Emotional

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	34.4 (± 13.11)	36.4 (± 10.77)	35.2 (± 10.73)	36.1 (± 12.46)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	35.3 (± 12.54)	37.4 (± 10.99)	36.1 (± 11.39)	38.9 (± 12.06)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	40.6 (± 11.13)	43.3 (± 12.95)	38.9 (± 12.64)	40.9 (± 10.8)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	40.5 (± 11.7)	42.9 (± 12.44)	39.7 (± 12.63)	42.7 (± 11.43)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	41 (± 11.23)	43.1 (± 11.58)	39.7 (± 12.14)	41.7 (± 11.66)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	40.5 (± 12.27)	41.4 (± 13)	37.7 (± 11.7)	40.4 (± 12.11)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health Component Score

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health Component Score

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	35.9 (± 12.47)	37.8 (± 10.91)	37.3 (± 10.11)	40 (± 11.86)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health Component Score

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health Component Score

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	41.1 (± 11.01)	43.3 (± 12.95)	39.9 (± 11.52)	40.4 (± 10.79)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health Component Score

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health Component Score

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	40.2 (± 11.36)	43.7 (± 11.41)	40.6 (± 12.35)	42.8 (± 10.82)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health Component Score

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health Component Score

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	40.7 (± 11.06)	43.1 (± 11.31)	40.9 (± 11.66)	41.7 (± 11.35)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health Component Score

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Mental Health Component Score

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	40.4 (± 11.98)	42.3 (± 12.1)	39.3 (± 11.14)	41.1 (± 11.92)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Component Score

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Component Score

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Baseline

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	32.1 (± 6.06)	32.8 (± 5.91)	32.9 (± 6.3)	33.9 (± 6.98)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Component Score

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical

	Component Score

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 4

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	35.3 (± 7.47)	36.6 (± 7.73)	37.1 (± 7.08)	40.5 (± 7.57)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Component Score

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Component Score

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 8

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	35.8 (± 7.59)	38.1 (± 8.12)	37.2 (± 6.73)	40 (± 8.78)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Component Score

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Component Score

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:

Week 12

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	36.5 (± 8.26)	38.3 (± 8.82)	38.2 (± 8.65)	40.3 (± 8.16)

Statistical analyses

No statistical analyses for this end point

Secondary: SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Component Score

End point title	SF-36 Health Questionnaire - Version 2 (SF-36v2) - Physical Component Score

End point description:

The SF-36v2 (Acute version) is a 36-item generic health status measure that yields an 8-scale profile of functional health and well-being as well as psychometrically-based physical and mental health summary measures.

The SF-36v2 consists of eight scaled scores, which are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale. The lower the score the more disability, while the higher the score the less disability.

End point type	Secondary

End point timeframe:
Week 16 (Follow-up)

End point values	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd	ARRY-438162: 20 mg bid
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	48	49	50
Units: units on a scale				
arithmetic mean (standard deviation)	37.1 (± 9.5)	37.6 (± 7.34)	37.2 (± 7.95)	39 (± 7.96)

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Treatment Emergent Adverse Events (TEAEs) were collected during the study, which began in April, 2008 and concluded in July, 2009.

All patients who were enrolled in the study and received at least one dose of study drug were included in AE reporting.

Adverse event reporting additional description:

An AE is any untoward medical occurrence including the exacerbation of a pre-existing condition, in a patient or clinical investigation subject administered a pharmaceutical product. This does not necessarily have a causal relationship with this treatment.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	11.0

Reporting groups

Reporting group title	Placebo

Reporting group description:

Placebo tablets were identical in appearance to both the 10 mg and 20 mg ARRY-438162 tablets.

Patients were randomized in a 1:1:1:1 fashion to ARRY-438162 10 mg bid, 40 mg qd or 20 mg bid, or placebo.

Reporting group title	ARRY-438162: 10 mg bid

Reporting group description:

Patients were randomized in a 1:1:1:1 fashion to ARRY-438162 10 mg bid, 40 mg qd or 20 mg bid, or placebo.

Reporting group title	ARRY-438162: 40 mg qd

Reporting group description:

Patients were randomized in a 1:1:1:1 fashion to ARRY-438162 10 mg bid, 40 mg qd or 20 mg bid, or placebo.

Reporting group title	ARRY-438162: 20 mg bid

Reporting group description:

Patients were randomized in a 1:1:1:1 fashion to ARRY-438162 10 mg bid, 40 mg qd or 20 mg bid, or placebo.

Serious adverse events	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 49 (2.04%)	1 / 49 (2.04%)	1 / 50 (2.00%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
ABDOMINAL INJURY			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (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
CHEST INJURY			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (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
Vascular disorders			
THROMBOPHLEBITIS			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ATRIAL FIBRILLATION			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
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 assessment type: Systematic			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Gastrointestinal disorders			
EROSIVE OESOPHAGITIS			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTRITIS EROSIVE			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
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			
BRONCHOPNEUMONIA			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (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
PNEUMONIA			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	ARRY-438162: 20 mg bid		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 50 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
ABDOMINAL INJURY			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
CHEST INJURY			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
THROMBOPHLEBITIS			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
ATRIAL FIBRILLATION			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
MYOCARDIAL INFARCTION			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
EROSIVE OESOPHAGITIS			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
GASTRITIS EROSIVE			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
BRONCHOPNEUMONIA			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
PNEUMONIA			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 50 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Placebo	ARRY-438162: 10 mg bid	ARRY-438162: 40 mg qd
Total subjects affected by non-serious adverse events			
subjects affected / exposed	20 / 49 (40.82%)	25 / 49 (51.02%)	39 / 50 (78.00%)
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	1 / 49 (2.04%)	2 / 49 (4.08%)	1 / 50 (2.00%)
occurrences (all)	1	2	1
HYPOTENSION			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
PHLEBITIS			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
THROMBOPHLEBITIS			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
VASCULITIS			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
OEDEMA PERIPHERAL			
subjects affected / exposed	1 / 49 (2.04%)	1 / 49 (2.04%)	3 / 50 (6.00%)
occurrences (all)	1	1	3
FACE OEDEMA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
FATIGUE			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1

GENERALISED OEDEMA			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	1 / 50 (2.00%)
occurrences (all)	0	1	1
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
PYREXIA			
subjects affected / exposed	1 / 49 (2.04%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	1	1	0
THIRST			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
ASTHENIA			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
GENITAL DISCHARGE			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
HYPOMENORRHOEA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
ALLERGIC SINUSITIS			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
EPISTAXIS			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
HYPOXIA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
PHARYNGOLARYNGEAL PAIN			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
UPPER RESPIRATORY TRACT			

INFLAMMATION			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
INSOMNIA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Investigations			
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 49 (0.00%)	4 / 49 (8.16%)	5 / 50 (10.00%)
occurrences (all)	0	4	5
BLOOD PRESSURE INCREASED			
subjects affected / exposed	0 / 49 (0.00%)	2 / 49 (4.08%)	1 / 50 (2.00%)
occurrences (all)	0	2	1
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
TRANSAMINASES INCREASED			
subjects affected / exposed	2 / 49 (4.08%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	2	1	0
WEIGHT INCREASED			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
BLOOD PRESSURE SYSTOLIC ABNORMAL			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
ELECTROCARDIOGRAM REPOLARISATION ABNORMALITY			

subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
HEPATIC ENZYME INCREASED			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
BLOOD GLUCOSE INCREASED			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
OSTEOARTHRITIS			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	0 / 49 (0.00%)	2 / 49 (4.08%)	1 / 50 (2.00%)
occurrences (all)	0	2	1
ABDOMINAL INJURY			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
ARTHROPOD BITE			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
CHEST INJURY			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
CONTUSION			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	1	0	1
EXCORIATION			

subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
JOINT INJURY			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
ATRIOVENTRICULAR BLOCK			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
LEFT VENTRICULAR HYPERTROPHY			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
MITRAL VALVE INCOMPETENCE			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
MYOCARDIAL ISCHAEMIA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
PALPITATIONS			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
TACHYCARDIA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
TRICUSPID VALVE INCOMPETENCE			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
MYOCARDIAL INFARCTION			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0

Nervous system disorders			
HEADACHE			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	3 / 50 (6.00%)
occurrences (all)	0	1	3
DIZZINESS			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
HYPOTONIA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
SCIATICA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
SOMNOLENCE			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
TREMOR			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
LYMPHOCYTOSIS			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
NEUTROPENIA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
SPONTANEOUS HAEMATOMA			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	2 / 50 (4.00%)
occurrences (all)	0	1	2
Eye disorders			
CONJUNCTIVAL HAEMORRHAGE			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	1 / 50 (2.00%)
occurrences (all)	0	1	1

CONJUNCTIVITIS			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
EYE SWELLING			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
SCOTOMA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
VISUAL ACUITY REDUCED			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	5 / 49 (10.20%)	3 / 49 (6.12%)	15 / 50 (30.00%)
occurrences (all)	5	3	15
NAUSEA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	6 / 50 (12.00%)
occurrences (all)	0	0	6
ABDOMINAL PAIN UPPER			
subjects affected / exposed	2 / 49 (4.08%)	0 / 49 (0.00%)	3 / 50 (6.00%)
occurrences (all)	2	0	3
GASTRITIS			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	3 / 50 (6.00%)
occurrences (all)	0	1	3
DYSPEPSIA			
subjects affected / exposed	1 / 49 (2.04%)	2 / 49 (4.08%)	2 / 50 (4.00%)
occurrences (all)	1	2	2
VOMITING			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	3 / 50 (6.00%)
occurrences (all)	0	1	3
ABDOMINAL PAIN			
subjects affected / exposed	1 / 49 (2.04%)	1 / 49 (2.04%)	1 / 50 (2.00%)
occurrences (all)	1	1	1
APHTHOUS STOMATITIS			

subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
ENTEROCOLITIS			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	1 / 50 (2.00%)
occurrences (all)	0	1	1
FLATULENCE			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
STOMATITIS			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
ANAL FISSURE			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
CHEILITIS			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
EROSIVE OESOPHAGITIS			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
FOOD POISONING			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
GASTRITIS EROSIVE			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
IRRITABLE BOWEL SYNDROME			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
TONGUE DISORDER			

subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
TOOTHACHE			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
HAEMORRHOIDAL HAEMORRHAGE			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
HIATUS HERNIA			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
CHOLELITHIASIS			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	2 / 49 (4.08%)	1 / 49 (2.04%)	7 / 50 (14.00%)
occurrences (all)	2	1	7
DERMATITIS ACNEIFORM			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
ACNE			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
ROSACEA			
subjects affected / exposed	0 / 49 (0.00%)	2 / 49 (4.08%)	0 / 50 (0.00%)
occurrences (all)	0	2	0
URTICARIA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
ALOPECIA			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	1 / 50 (2.00%)
occurrences (all)	0	1	1
ECZEMA			

subjects affected / exposed	0 / 49 (0.00%)	2 / 49 (4.08%)	0 / 50 (0.00%)
occurrences (all)	0	2	0
PRURITUS			
subjects affected / exposed	2 / 49 (4.08%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	2	0	0
RASH ERYTHEMATOUS			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
RASH PAPULAR			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
SKIN ULCER			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
ECCHYMOSIS			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
ERYTHEMA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
LIVEDO RETICULARIS			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
ONYCHOCLASIS			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
PERIORBITAL OEDEMA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
PIGMENTATION DISORDER			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
PLANTAR ERYTHEMA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
PRURIGO			

subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
DYSURIA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
URINARY BLADDER POLYP			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
HAEMATURIA			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
PROTEINURIA			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
RENAL COLIC			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
RHEUMATOID ARTHRITIS			
subjects affected / exposed	5 / 49 (10.20%)	2 / 49 (4.08%)	5 / 50 (10.00%)
occurrences (all)	5	2	5
BACK PAIN			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	1	0	1
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
BONE PAIN			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
SYNOVIAL CYST			

subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
ARTHRALGIA			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
URINARY TRACT INFECTION			
subjects affected / exposed	4 / 49 (8.16%)	4 / 49 (8.16%)	2 / 50 (4.00%)
occurrences (all)	4	4	2
BRONCHITIS			
subjects affected / exposed	2 / 49 (4.08%)	2 / 49 (4.08%)	1 / 50 (2.00%)
occurrences (all)	2	2	1
FOLLICULITIS			
subjects affected / exposed	0 / 49 (0.00%)	3 / 49 (6.12%)	1 / 50 (2.00%)
occurrences (all)	0	3	1
GASTROENTERITIS			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	2 / 50 (4.00%)
occurrences (all)	0	1	2
RASH PUSTULAR			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	1 / 50 (2.00%)
occurrences (all)	0	1	1
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	2 / 50 (4.00%)
occurrences (all)	0	0	2
CYSTITIS			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	1 / 50 (2.00%)
occurrences (all)	0	1	1
INFLUENZA			
subjects affected / exposed	3 / 49 (6.12%)	1 / 49 (2.04%)	1 / 50 (2.00%)
occurrences (all)	3	1	1
ACUTE TONSILLITIS			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
BRONCHOPNEUMONIA			

subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
EAR INFECTION			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
GASTROENTERITIS VIRAL			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
GENITAL HERPES			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
HELICOBACTER GASTRITIS			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
HERPES SIMPLEX			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
NASOPHARYNGITIS			
subjects affected / exposed	4 / 49 (8.16%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	4	0	0
PARONYCHIA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
PHARYNGITIS			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
PHARYNGOTONSILLITIS			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
PNEUMONIA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
TRACHEITIS			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
TRACHEOBRONCHITIS			

subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
ASYMPTOMATIC BACTERIURIA			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	0 / 49 (0.00%)	1 / 49 (2.04%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
DYSLIPIDAEMIA			
subjects affected / exposed	0 / 49 (0.00%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
VITAMIN D DEFICIENCY			
subjects affected / exposed	1 / 49 (2.04%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	ARRY-438162: 20 mg bid		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	42 / 50 (84.00%)		
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		
HYPOTENSION			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
PHLEBITIS			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
THROMBOPHLEBITIS			

subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
VASCULITIS			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
OEDEMA PERIPHERAL			
subjects affected / exposed	3 / 50 (6.00%)		
occurrences (all)	3		
FACE OEDEMA			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
FATIGUE			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
GENERALISED OEDEMA			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
INFLUENZA LIKE ILLNESS			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
PYREXIA			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
THIRST			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
ASTHENIA			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
GENITAL DISCHARGE			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
HYPOMENORRHOEA			

subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
ALLERGIC SINUSITIS			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
EPISTAXIS			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
HYPOXIA			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
PHARYNGOLARYNGEAL PAIN			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
UPPER RESPIRATORY TRACT INFLAMMATION			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
Psychiatric disorders			
INSOMNIA			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Investigations			
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	5 / 50 (10.00%)		
occurrences (all)	5		
BLOOD PRESSURE INCREASED			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences (all)	2		
TRANSAMINASES INCREASED			

subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
WEIGHT INCREASED			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
BLOOD PRESSURE SYSTOLIC ABNORMAL			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
ELECTROCARDIOGRAM QT PROLONGED			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
ELECTROCARDIOGRAM REPOLARISATION ABNORMALITY			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
GAMMA-GLUTAMYLTRANSFERASE INCREASED			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
HEPATIC ENZYME INCREASED			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
LIVER FUNCTION TEST ABNORMAL			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
BLOOD GLUCOSE INCREASED			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
OSTEOARTHRITIS			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			

FALL			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
ABDOMINAL INJURY			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
ARTHROPOD BITE			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
CHEST INJURY			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
CONTUSION			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
EXCORIATION			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
JOINT INJURY			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
ANGINA PECTORIS			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
ATRIAL FIBRILLATION			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
ATRIOVENTRICULAR BLOCK			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
LEFT VENTRICULAR HYPERTROPHY			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
MITRAL VALVE INCOMPETENCE			

subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
MYOCARDIAL ISCHAEMIA			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
PALPITATIONS			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
TACHYCARDIA			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
TRICUSPID VALVE INCOMPETENCE			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
HEADACHE			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
DIZZINESS			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
HYPOTONIA			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
SCIATICA			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
SOMNOLENCE			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
TREMOR			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		

Blood and lymphatic system disorders			
LYMPHOCYTOSIS			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
NEUTROPENIA			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
SPONTANEOUS HAEMATOMA			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Eye disorders			
CONJUNCTIVAL HAEMORRHAGE			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
CONJUNCTIVITIS			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
EYE SWELLING			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
SCOTOMA			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
VISUAL ACUITY REDUCED			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	12 / 50 (24.00%)		
occurrences (all)	12		
NAUSEA			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences (all)	2		

ABDOMINAL PAIN UPPER				
subjects affected / exposed	3 / 50 (6.00%)			
occurrences (all)	3			
GASTRITIS				
subjects affected / exposed	2 / 50 (4.00%)			
occurrences (all)	2			
DYSPEPSIA				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences (all)	1			
VOMITING				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences (all)	0			
ABDOMINAL PAIN				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences (all)	1			
APHTHOUS STOMATITIS				
subjects affected / exposed	2 / 50 (4.00%)			
occurrences (all)	2			
DRY MOUTH				
subjects affected / exposed	2 / 50 (4.00%)			
occurrences (all)	2			
ENTEROCOLITIS				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences (all)	0			
FLATULENCE				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences (all)	1			
STOMATITIS				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences (all)	1			
ABDOMINAL DISTENSION				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences (all)	0			
ANAL FISSURE				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences (all)	0			

CHEILITIS subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1		
EROSIVE OESOPHAGITIS subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
FOOD POISONING subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
GASTRITIS EROSIVE subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
IRRITABLE BOWEL SYNDROME subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
TONGUE DISORDER subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
TOOTHACHE subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1		
HAEMORRHOIDAL HAEMORRHAGE subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
HIATUS HERNIA subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Hepatobiliary disorders CHOLELITHIASIS subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		
Skin and subcutaneous tissue disorders RASH subjects affected / exposed occurrences (all)	5 / 50 (10.00%) 5		
DERMATITIS ACNEIFORM			

subjects affected / exposed	5 / 50 (10.00%)			
occurrences (all)	5			
ACNE				
subjects affected / exposed	2 / 50 (4.00%)			
occurrences (all)	2			
ROSACEA				
subjects affected / exposed	2 / 50 (4.00%)			
occurrences (all)	2			
URTICARIA				
subjects affected / exposed	2 / 50 (4.00%)			
occurrences (all)	2			
ALOPECIA				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences (all)	1			
ECZEMA				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences (all)	0			
PRURITUS				
subjects affected / exposed	2 / 50 (4.00%)			
occurrences (all)	2			
RASH ERYTHEMATOUS				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences (all)	1			
RASH PAPULAR				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences (all)	1			
SKIN ULCER				
subjects affected / exposed	2 / 50 (4.00%)			
occurrences (all)	2			
ECCHYMOSIS				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences (all)	0			
ERYTHEMA				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences (all)	1			
LIVEDO RETICULARIS				

subjects affected / exposed occurrences (all) ONYCHOCLASIS subjects affected / exposed occurrences (all) PERIORBITAL OEDEMA subjects affected / exposed occurrences (all) PIGMENTATION DISORDER subjects affected / exposed occurrences (all) PLANTAR ERYTHEMA subjects affected / exposed occurrences (all) PRURIGO subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0 0 / 50 (0.00%) 0 1 / 50 (2.00%) 1 1 / 50 (2.00%) 1 1 / 50 (2.00%) 1 0 / 50 (0.00%) 0		
Renal and urinary disorders DYSURIA subjects affected / exposed occurrences (all) URINARY BLADDER POLYP subjects affected / exposed occurrences (all) HAEMATURIA subjects affected / exposed occurrences (all) PROTEINURIA subjects affected / exposed occurrences (all) RENAL COLIC subjects affected / exposed occurrences (all)	 1 / 50 (2.00%) 1 0 / 50 (0.00%) 0 0 / 50 (0.00%) 0 0 / 50 (0.00%) 0 0 / 50 (0.00%) 0		
Musculoskeletal and connective tissue disorders			

RHEUMATOID ARTHRITIS			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences (all)	2		
BACK PAIN			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences (all)	2		
MUSCULOSKELETAL PAIN			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
BONE PAIN			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
MUSCULOSKELETAL CHEST PAIN			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
SYNOVIAL CYST			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
ARTHRALGIA			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Infections and infestations			
URINARY TRACT INFECTION			
subjects affected / exposed	5 / 50 (10.00%)		
occurrences (all)	5		
BRONCHITIS			
subjects affected / exposed	4 / 50 (8.00%)		
occurrences (all)	4		
FOLLICULITIS			
subjects affected / exposed	2 / 50 (4.00%)		
occurrences (all)	2		
GASTROENTERITIS			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
RASH PUSTULAR			

subjects affected / exposed	2 / 50 (4.00%)			
occurrences (all)	2			
UPPER RESPIRATORY TRACT INFECTION				
subjects affected / exposed	2 / 50 (4.00%)			
occurrences (all)	2			
CYSTITIS				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences (all)	0			
INFLUENZA				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences (all)	0			
ACUTE TONSILLITIS				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences (all)	1			
BRONCHOPNEUMONIA				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences (all)	0			
EAR INFECTION				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences (all)	1			
GASTROENTERITIS VIRAL				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences (all)	0			
GENITAL HERPES				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences (all)	0			
HELICOBACTER GASTRITIS				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences (all)	0			
HERPES SIMPLEX				
subjects affected / exposed	0 / 50 (0.00%)			
occurrences (all)	0			
NASOPHARYNGITIS				
subjects affected / exposed	1 / 50 (2.00%)			
occurrences (all)	1			

PARONYCHIA			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
PHARYNGITIS			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
PHARYNGOTONSILLITIS			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
PNEUMONIA			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
TRACHEITIS			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
TRACHEOBRONCHITIS			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
VULVOVAGINAL MYCOTIC INFECTION			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
ASYMPTOMATIC BACTERIURIA			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
VIRAL UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	0 / 50 (0.00%)		
occurrences (all)	0		
DYSLIPIDAEMIA			
subjects affected / exposed	1 / 50 (2.00%)		
occurrences (all)	1		
VITAMIN D DEFICIENCY			

subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 January 2008	Amendment 1 had the following changes: • Remove the Multidimensional Assessment of Fatigue (MAF) questionnaire. • Remove the erythrocyte sedimentation rate (ESR) lab requirement due to stability issues with the assay at the central laboratory. • Clarify the PK section by adding the measurement of plasma concentrations of metabolite AR00426032 and methotrexate. • Correct discrepancies between windows for visit days and the actual days of visits. • Remove the language "in descending order" regarding the list of assessments on clinic visit days and to rearrange order of assessments so that questionnaires may be completed in order. • Add anti-CCP and rheumatoid factor to the list of clinical labs after they were unintentionally omitted from the original protocol. • Remove fasting status for glucose because fasting was not required. • Remove antimalarials from the list of prohibited concomitant medications.
30 May 2008	Amendment 2 had the following changes: • Reflect a change in the Interim Analysis Plan that removed one of the interim analyses. • Reflect a change in the Interim Analysis Plan. • Include the Head of Biostatistics as a member of the RMC. • Include gastrointestinal events as a body system the Medical Monitor would be reviewing. • Update the Visual Analogue Scales. • Clarify that the SF-36 Health Survey should be completed prior to any procedures being performed at the visit. • Expand the inclusion criteria list of permitted biological agents. • Update inclusion criterion 9c. • Update exclusionary body temperatures. • Update the AEs and breaking the blind sections. • Remove the first footnote in the schedule of events table in the synopsis. • Update the study rationale section to reflect the contents of Hungarian local amendment. • Remove "tolerability" from the evaluations of safety included in the study objectives. • Update the definition of examination of the acneiform skin exanthema in the Dermatological Safety Management Table. • Update the Gastrointestinal Safety Management Table. • Add a safety management plan for infections if an AE was observed. • Clarify the Institutional Review Board section. • Update the prohibited concomitant medications appendix.
27 August 2008	Amendment 3 had the following changes: • Reflect a change in Medical Monitor due to a change in personnel. • Clarify the acceptable birth control methods for female patients to include condom plus spermicidal foam/gel.

Notes:

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.

N/A

Notes: