Clinical trial results:
A randomized, double-blind, placebo-controlled, multicenter, parallel group, dose-finding, pivotal, Phase 2b/3 study to evaluate the efficacy, safety, and tolerability of intravenous BYM338 at 52 weeks on physical function, muscle strength, and mobility and additional long-term safety up to 2 years in patients with sporadic inclusion body myositis

Summary

EudraCT number	2013-000705-23
Trial protocol	IT NL DE BE GB DK
Global end of trial date	06 January 2016

Results information

Result version number	v2 (current)
This version publication date	31 May 2017
First version publication date	21 January 2017
Version creation reason	• New data added to full data set • Correction of full data set Title updated and new data added to secondary end point (EP) #2 (LBM); description updated for secondary EP #4 (sIFA); and title and unit updated in EP#5 (Falls).

Trial information

Trial identification

Sponsor protocol code	CBYM338B2203

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01925209
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Novartis Pharma AG
Sponsor organisation address	CH-4002, Basel, Switzerland,
Public contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111,
Scientific contact	Clinical Disclosure Office, Novartis Pharma AG, 41 613241111,

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	06 January 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 January 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to demonstrate that at least one dose regimen of bimagrumab in ambulatory sporadic inclusion body myositis (sIBM) patients increased the distance traveled, as measured by change from baseline at Week 52 of the 6MWD test relative to placebo.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 September 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 42
Country: Number of subjects enrolled	Belgium: 9
Country: Number of subjects enrolled	Denmark: 14
Country: Number of subjects enrolled	France: 10
Country: Number of subjects enrolled	United Kingdom: 29
Country: Number of subjects enrolled	Italy: 14
Country: Number of subjects enrolled	Japan: 20
Country: Number of subjects enrolled	Netherlands: 18
Country: Number of subjects enrolled	Switzerland: 1
Country: Number of subjects enrolled	United States: 94
Worldwide total number of subjects	251
EEA total number of subjects	94

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)	75
From 65 to 84 years	175
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Participants were randomized into one of the four treatment arms in a 1:1:1:1 ratio.

Pre-assignment

Screening details:

The study included 4 epochs: screening (up to 28 days pre-treatment), treatment (from day 1 up to 52 weeks), treatment maintenance (from week 52 up to 104 weeks) and follow-up (28 days after last dose administration). The disposition data reported are for the treatment epoch.

Period 1

Period 1 title	Treatment Epoch (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	BYM338/bimagrumab 10 mg/kg

Arm description:

Participants received study medication with BYM338 at 10 mg/kg from Day 1 to Week 52 and up to Week 104, administered by intravenous (i.v.) infusion every 4 weeks.

Arm type	Experimental
Investigational medicinal product name	Bimagrumab
Investigational medicinal product code	BYM338
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received BYM338 at 10 mg/kg intravenous (i.v.) infusion every 4 weeks from Day 1 to Week 52, and up to Week 104.

Arm title	BYM338/bimagrumab 3 mg/kg

Arm description:

Participants received study medication with BYM338 at 3 mg/kg from Day 1 to Week 52 and up to Week 104, administered by i.v. infusion every 4 weeks.

Arm type	Experimental
Investigational medicinal product name	Bimagrumab
Investigational medicinal product code	BYM338
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received BYM338 at 3 mg/kg i.v. infusion every 4 weeks from Day 1 to Week 52, and up to Week 104.

Arm title	BYM338/bimagrumab 1 mg/kg

Arm description:

Participants received study medication with BYM338 at 1 mg/kg from Day 1 to Week 52 and up to Week

104, administered by i.v. infusion every 4 weeks.

Arm type	Experimental
Investigational medicinal product name	Bimagrumab
Investigational medicinal product code	BYM338
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received BYM338 at 1 mg/kg i.v. infusion every 4 weeks from Day 1 to Week 52, and up to Week 104.

Arm title	Placebo

Arm description:

Participants received matching placebo to BYM338 from Day 1 to Week 52 and up to Week 104, administered by i.v. infusion every 4 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received matching placebo to BYM338 i.v. infusion every 4 weeks from Day 1 to Week 52, and up to Week 104.

Number of subjects in period 1	BYM338/bimagrumab 10 mg/kg	BYM338/bimagrumab 3 mg/kg	BYM338/bimagrumab 1 mg/kg
Started	63	63	63
Full Analysis Set	63	63	63
Completed	54	55	56
Not completed	9	8	7
Adverse event, serious fatal	1	-	-
Physician decision	1	-	-
Adverse event, non-fatal	3	5	3
Protocol deviation	-	-	1
Non-compliance with study treatment	-	-	-
Withdrawal by subject	4	3	3

Number of subjects in period 1	Placebo
Started	62
Full Analysis Set	62
Completed	57
Not completed	5
Adverse event, serious fatal	-

Physician decision	-
Adverse event, non-fatal	1
Protocol deviation	1
Non-compliance with study treatment	1
Withdrawal by subject	2

Baseline characteristics

Reporting groups	
Reporting group title	BYM338/bimagrumab 10 mg/kg

Reporting group description:

Participants received study medication with BYM338 at 10 mg/kg from Day 1 to Week 52 and up to Week 104, administered by intravenous (i.v.) infusion every 4 weeks.

Reporting group title	BYM338/bimagrumab 3 mg/kg

Reporting group description:

Participants received study medication with BYM338 at 3 mg/kg from Day 1 to Week 52 and up to Week 104, administered by i.v. infusion every 4 weeks.

Reporting group title	BYM338/bimagrumab 1 mg/kg

Reporting group description:

Participants received study medication with BYM338 at 1 mg/kg from Day 1 to Week 52 and up to Week 104, administered by i.v. infusion every 4 weeks.

Reporting group title	Placebo

Reporting group description:

Participants received matching placebo to BYM338 from Day 1 to Week 52 and up to Week 104, administered by i.v. infusion every 4 weeks.

Reporting group values	BYM338/bimagrumab 10 mg/kg	BYM338/bimagrumab 3 mg/kg	BYM338/bimagrumab 1 mg/kg
Number of subjects	63	63	63
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	16	27	14
From 65-84 years	47	36	48
85 years and over	0	0	1
Age Continuous Units: Years			
arithmetic mean	68	66.5	69.4
standard deviation	± 7.93	± 8.72	± 7.91
Gender, Male/Female Units: Subjects			
Female	22	21	23
Male	41	42	40

Reporting group values	Placebo	Total	

Number of subjects	62	251	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	18	75	
From 65-84 years	44	175	
85 years and over	0	1	
Age Continuous Units: Years			
arithmetic mean	68.4		
standard deviation	± 8.12	-	
Gender, Male/Female Units: Subjects			
Female	23	89	
Male	39	162	

End points

End points reporting groups

Reporting group title	BYM338/bimagrumab 10 mg/kg

Reporting group description:

Participants received study medication with BYM338 at 10 mg/kg from Day 1 to Week 52 and up to Week 104, administered by intravenous (i.v.) infusion every 4 weeks.

Reporting group title	BYM338/bimagrumab 3 mg/kg

Reporting group description:

Participants received study medication with BYM338 at 3 mg/kg from Day 1 to Week 52 and up to Week 104, administered by i.v. infusion every 4 weeks.

Reporting group title	BYM338/bimagrumab 1 mg/kg

Reporting group description:

Participants received study medication with BYM338 at 1 mg/kg from Day 1 to Week 52 and up to Week 104, administered by i.v. infusion every 4 weeks.

Reporting group title	Placebo

Reporting group description:

Participants received matching placebo to BYM338 from Day 1 to Week 52 and up to Week 104, administered by i.v. infusion every 4 weeks.

Primary: Change from Baseline in 6 Minute Walking Distance (6MWD) Test at week 52

End point title	Change from Baseline in 6 Minute Walking Distance (6MWD) Test at week 52

End point description:

The 6MWD test measured the distance (in meters) that a participant walked in a 6 minute timeframe. A positive change from baseline indicates improvement.

End point type	Primary

End point timeframe:

Baseline, Week 52

End point values	BYM338/bimagrumab 10 mg/kg	BYM338/bimagrumab 3 mg/kg	BYM338/bimagrumab 1 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	63	63	62
Units: meters				
least squares mean (standard error)	8.63 (± 10.934)	9.63 (± 10.77)	-10.27 (± 10.718)	-8.96 (± 10.765)

Statistical analyses

Statistical analysis title	Change from Baseline in 6MWD at week 52
Comparison groups	BYM338/bimagrumab 10 mg/kg v Placebo
Number of subjects included in analysis	123
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.221
Method	mixed model repeated measures
Parameter estimate	Mean difference (net)
Point estimate	17.59
Confidence interval	
level	Other: 99 %
sides	2-sided
lower limit	-19.63
upper limit	54.8
Variability estimate	Standard error of the mean
Dispersion value	14.331

Statistical analysis title	Change from Baseline in 6MWD at week 52
Comparison groups	BYM338/bimagrumab 3 mg/kg v Placebo
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1909
Method	mixed model repeated measure
Parameter estimate	Mean difference (net)
Point estimate	18.59
Confidence interval	
level	Other: 99 %
sides	2-sided
lower limit	-18.21
upper limit	55.4
Variability estimate	Standard error of the mean
Dispersion value	14.176

Statistical analysis title	Change from Baseline in 6MWD at week 52
Comparison groups	BYM338/bimagrumab 1 mg/kg v Placebo
Number of subjects included in analysis	125
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.9263
Method	mixed models repeated measures
Parameter estimate	Mean difference (net)
Point estimate	-1.31

Confidence interval	
level	Other: 99 %
sides	2-sided
lower limit	-37.97
upper limit	35.36
Variability estimate	Standard error of the mean
Dispersion value	14.121

Secondary: Estimated within treatment group lean body mass (LBM) ratio at week 52

End point title	Estimated within treatment group lean body mass (LBM) ratio at week 52

End point description:

LBM was measured via dual energy x-ray absorptiometry (DXA) and calculated as (LBM at Week 52/LBM at baseline)*100 . A positive change from baseline indicates improvement.

End point type	Secondary

End point timeframe:

Baseline, Week 52

End point values	BYM338/bimagrumab 10 mg/kg	BYM338/bimagrumab 3 mg/kg	BYM338/bimagrumab 1 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	61	63	61
Units: Percentage				
number (confidence interval 95%)	102.8 (101.4 to 104.2)	100.4 (99.1 to 101.8)	98.3 (97 to 99.6)	97.2 (95.9 to 98.5)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in quadriceps Quantitative Muscle Testing (QMT) on the right side at week 52

End point title	Change from Baseline in quadriceps Quantitative Muscle Testing (QMT) on the right side at week 52

End point description:

Quadriceps muscle strength was measured by portable fixed dynamometry (PFD) on the right side. A negative change from baseline indicates deterioration.

End point type	Secondary

End point timeframe:

Baseline, Week 52

End point values	BYM338/bimagrumab 10 mg/kg	BYM338/bimagrumab 3 mg/kg	BYM338/bimagrumab 1 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	63	63	61
Units: newtons				
least squares mean (standard error)	-12.44 (± 6.021)	-20.36 (± 5.843)	-14.89 (± 5.828)	-16.48 (± 5.83)

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in sIBM functional assessment (sIFA) at week 52

End point title	Change from baseline in sIBM functional assessment (sIFA) at week 52

End point description:

Self-reported physical function was assessed by a newly developed patient reported outcome named sporadic inclusion body myositis (sIBM) functional assessment (sIFA). The sIFA consists of 11 items scored on an 11 point numerical rating scale from 0 (no difficulty) to 10 (unable to do) across 3 domains: upper body functioning, lower body functioning and general functioning. Participants completed the assessment where the recall period was the past week prior to completing the patient reported outcome (PRO). The total score on the sIFA scale ranges from 0 (minimum) to 110 (maximum). Higher values represent a worse outcome. A positive change from baseline indicates deterioration.

End point type	Secondary

End point timeframe:

Baseline, Week 52

End point values	BYM338/bimagrumab 10 mg/kg	BYM338/bimagrumab 3 mg/kg	BYM338/bimagrumab 1 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	61	63	60	61
Units: score on a scale				
least squares mean (standard error)	1.74 (± 1.915)	3.56 (± 1.876)	6.12 (± 1.899)	6.85 (± 1.895)

Statistical analyses

No statistical analyses for this end point

Secondary: Estimated annual number of falls per participant within treatment group

End point title	Estimated annual number of falls per participant within treatment group

End point description:

Participants documented any fall occurrences in a paper diary during the study.

End point type	Secondary

End point timeframe:

Week 52

End point values	BYM338/bimagrumab 10 mg/kg	BYM338/bimagrumab 3 mg/kg	BYM338/bimagrumab 1 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	63	63	63	62
Units: Annual number of falls per participant				
number (not applicable)	4.33	4.02	4.7	5.13

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in Short Physical Performance Battery (SPPB) score at week 52

End point title	Change from Baseline in Short Physical Performance Battery (SPPB) score at week 52

End point description:

The SPPB evaluated lower extremities function by testing gait speed, ability to keep standing balance and time to rise from a chair five times. The sub-score for each test ranged from 0 to 4. The summary score, which was a summation of scores from the 3 tests, ranged from 0 to 12. An increase in score indicates improvement in physical performance. A negative change from baseline indicates deterioration.

End point type	Secondary

End point timeframe:

Baseline, Week 52

End point values	BYM338/bimagrumab 10 mg/kg	BYM338/bimagrumab 3 mg/kg	BYM338/bimagrumab 1 mg/kg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	63	63	62
Units: score on a scale				
least squares mean (standard error)	0 (± 0.24)	0 (± 0.23)	-0.5 (± 0.23)	-0.5 (± 0.23)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All adverse events reported in this record are from date of First Patient First Treatment until Last Patient Last Visit.

Adverse event reporting additional description:

Consistent with EudraCT disclosure specifications, Novartis has reported under the Serious adverse events field "number of deaths resulting from adverse events" all those deaths, resulting from serious adverse events that are deemed to be causally related to treatment by the investigator.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.1

Reporting groups

Reporting group title	BYM338 10 mg/kg
Reporting group description:	
BYM338 10 mg/kg	
Reporting group title	BYM338 3 mg/kg
Reporting group description:	
BYM338 3 mg/kg	
Reporting group title	BYM338 1 mg/kg
Reporting group description:	
BYM338 1 mg/kg	
Reporting group title	Placebo
Reporting group description:	
Placebo	

Serious adverse events	BYM338 10 mg/kg	BYM338 3 mg/kg	BYM338 1 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	21 / 63 (33.33%)	11 / 63 (17.46%)	18 / 63 (28.57%)
number of deaths (all causes)	1	0	1
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BASAL CELL CARCINOMA			
subjects affected / exposed	3 / 63 (4.76%)	3 / 63 (4.76%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 4	0 / 4	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LUNG ADENOCARCINOMA			

subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	2 / 63 (3.17%)	2 / 63 (3.17%)	2 / 63 (3.17%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SQUAMOUS CELL CARCINOMA OF SKIN			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
AORTIC ANEURYSM			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERIPHERAL ISCHAEMIA			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
INJURY ASSOCIATED WITH DEVICE			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ASPIRATION			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA ASPIRATION			

subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
DEPRESSION			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUICIDE ATTEMPT			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
ANKLE FRACTURE			

subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CARBON MONOXIDE POISONING			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CERVICAL VERTEBRAL FRACTURE			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ENDOTRACHEAL INTUBATION COMPLICATION			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
EYE INJURY			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FACIAL BONES FRACTURE			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FALL			
subjects affected / exposed	2 / 63 (3.17%)	2 / 63 (3.17%)	4 / 63 (6.35%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FEMUR FRACTURE			
subjects affected / exposed	0 / 63 (0.00%)	1 / 63 (1.59%)	0 / 63 (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
FIBULA FRACTURE			

subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOOT FRACTURE			
subjects affected / exposed	0 / 63 (0.00%)	1 / 63 (1.59%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAND FRACTURE			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HIP FRACTURE			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTENTIONAL OVERDOSE			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (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
LACERATION			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PATELLA FRACTURE			
subjects affected / exposed	0 / 63 (0.00%)	1 / 63 (1.59%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPINAL CORD INJURY CERVICAL			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
THORACIC VERTEBRAL FRACTURE			

subjects affected / exposed	0 / 63 (0.00%)	1 / 63 (1.59%)	0 / 63 (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
TIBIA FRACTURE			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	2 / 63 (3.17%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRAUMATIC HAEMATOMA			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VASCULAR PSEUDOANEURYSM			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WRIST FRACTURE			
subjects affected / exposed	0 / 63 (0.00%)	1 / 63 (1.59%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
ACUTE MYOCARDIAL INFARCTION			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIAL FIBRILLATION			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIOVENTRICULAR BLOCK			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ATRIOVENTRICULAR BLOCK SECOND DEGREE			

subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYOCARDIAL INFARCTION			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (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
PALPITATIONS			
subjects affected / exposed	0 / 63 (0.00%)	1 / 63 (1.59%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
CAROTID ARTERY STENOSIS			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PRESYNCOPE			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSIENT GLOBAL AMNESIA			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	0 / 63 (0.00%)	1 / 63 (1.59%)	0 / 63 (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
Blood and lymphatic system disorders			

ANAEMIA			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
RETINAL ARTERY OCCLUSION			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
ABDOMINAL DISTENSION			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL HERNIA			
subjects affected / exposed	0 / 63 (0.00%)	1 / 63 (1.59%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			

subjects affected / exposed	3 / 63 (4.76%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DYSPHAGIA			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INGUINAL HERNIA			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOLVULUS			
subjects affected / exposed	0 / 63 (0.00%)	1 / 63 (1.59%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
RASH PRURITIC			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
BLADDER MASS			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMATURIA			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY RETENTION			

subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MYALGIA			
subjects affected / exposed	0 / 63 (0.00%)	1 / 63 (1.59%)	0 / 63 (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
VERTEBRAL FORAMINAL STENOSIS			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
DIVERTICULITIS			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
STREPTOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 63 (0.00%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	1 / 63 (1.59%)	0 / 63 (0.00%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPONATRAEMIA			
subjects affected / exposed	1 / 63 (1.59%)	1 / 63 (1.59%)	0 / 63 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	20 / 62 (32.26%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
BASAL CELL CARCINOMA			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
LUNG ADENOCARCINOMA			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
SQUAMOUS CELL CARCINOMA			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
SQUAMOUS CELL CARCINOMA OF SKIN			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
AORTIC ANEURYSM			

subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PERIPHERAL ISCHAEMIA				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
INJURY ASSOCIATED WITH DEVICE				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
ASPIRATION				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PNEUMONIA ASPIRATION				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
PULMONARY EMBOLISM				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
DEPRESSION				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
SUICIDE ATTEMPT				

subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
ALANINE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
ASPARTATE AMINOTRANSFERASE INCREASED			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
BLOOD ALKALINE PHOSPHATASE INCREASED			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
ANKLE FRACTURE			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
CARBON MONOXIDE POISONING			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
CERVICAL VERTEBRAL FRACTURE			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
ENDOTRACHEAL INTUBATION COMPLICATION			

subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
EYE INJURY				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
FACIAL BONES FRACTURE				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
FALL				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
FEMUR FRACTURE				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
FIBULA FRACTURE				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
FOOT FRACTURE				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
HAND FRACTURE				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
HIP FRACTURE				

subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
INTENTIONAL OVERDOSE				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
LACERATION				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PATELLA FRACTURE				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
SPINAL CORD INJURY CERVICAL				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
THORACIC VERTEBRAL FRACTURE				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
TIBIA FRACTURE				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
TRAUMATIC HAEMATOMA				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
VASCULAR PSEUDOANEURYSM				

subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
WRIST FRACTURE				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
ACUTE MYOCARDIAL INFARCTION				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ATRIAL FIBRILLATION				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ATRIOVENTRICULAR BLOCK				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
ATRIOVENTRICULAR BLOCK SECOND DEGREE				
subjects affected / exposed	1 / 62 (1.61%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
MYOCARDIAL INFARCTION				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
PALPITATIONS				
subjects affected / exposed	0 / 62 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				

CAROTID ARTERY STENOSIS			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
PRESYNCOPE			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
SYNCOPE			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
TRANSIENT GLOBAL AMNESIA			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
TRANSIENT ISCHAEMIC ATTACK			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
IRON DEFICIENCY ANAEMIA			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Eye disorders			
RETINAL ARTERY OCCLUSION			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
ABDOMINAL DISTENSION			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
ABDOMINAL HERNIA			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
DIARRHOEA			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
DYSPHAGIA			
subjects affected / exposed	2 / 62 (3.23%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
INGUINAL HERNIA			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
VOLVULUS			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
RASH PRURITIC			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
BLADDER MASS			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
HAEMATURIA			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
URINARY RETENTION			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
MYALGIA			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
VERTEBRAL FORAMINAL STENOSIS			

subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
DIVERTICULITIS			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
PNEUMONIA			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
STREPTOCOCCAL BACTERAEMIA			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
DEHYDRATION			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
HYPONATRAEMIA			
subjects affected / exposed	0 / 62 (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: 5 %

Non-serious adverse events	BYM338 10 mg/kg	BYM338 3 mg/kg	BYM338 1 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	63 / 63 (100.00%)	63 / 63 (100.00%)	63 / 63 (100.00%)
Vascular disorders			
HAEMATOMA			
subjects affected / exposed	1 / 63 (1.59%)	2 / 63 (3.17%)	7 / 63 (11.11%)
occurrences (all)	1	2	9
HYPERTENSION			
subjects affected / exposed	7 / 63 (11.11%)	7 / 63 (11.11%)	5 / 63 (7.94%)
occurrences (all)	7	7	6
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	1 / 63 (1.59%)	3 / 63 (4.76%)	4 / 63 (6.35%)
occurrences (all)	1	3	4
FATIGUE			
subjects affected / exposed	9 / 63 (14.29%)	4 / 63 (6.35%)	14 / 63 (22.22%)
occurrences (all)	10	4	28
OEDEMA PERIPHERAL			
subjects affected / exposed	5 / 63 (7.94%)	9 / 63 (14.29%)	9 / 63 (14.29%)
occurrences (all)	6	11	9
PYREXIA			
subjects affected / exposed	3 / 63 (4.76%)	1 / 63 (1.59%)	3 / 63 (4.76%)
occurrences (all)	3	1	4
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	3 / 63 (4.76%)	3 / 63 (4.76%)	4 / 63 (6.35%)
occurrences (all)	3	3	4
DYSPNOEA			
subjects affected / exposed	2 / 63 (3.17%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences (all)	2	0	1
RHINORRHOEA			
subjects affected / exposed	4 / 63 (6.35%)	3 / 63 (4.76%)	5 / 63 (7.94%)
occurrences (all)	4	3	5
Psychiatric disorders			
ANXIETY			

subjects affected / exposed	4 / 63 (6.35%)	2 / 63 (3.17%)	1 / 63 (1.59%)
occurrences (all)	4	2	1
DEPRESSED MOOD			
subjects affected / exposed	4 / 63 (6.35%)	1 / 63 (1.59%)	0 / 63 (0.00%)
occurrences (all)	4	2	0
DEPRESSION			
subjects affected / exposed	4 / 63 (6.35%)	1 / 63 (1.59%)	5 / 63 (7.94%)
occurrences (all)	4	1	5
INSOMNIA			
subjects affected / exposed	5 / 63 (7.94%)	0 / 63 (0.00%)	2 / 63 (3.17%)
occurrences (all)	6	0	2
Investigations			
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	3 / 63 (4.76%)	5 / 63 (7.94%)	4 / 63 (6.35%)
occurrences (all)	3	5	4
VITAMIN D DECREASED			
subjects affected / exposed	4 / 63 (6.35%)	2 / 63 (3.17%)	3 / 63 (4.76%)
occurrences (all)	4	3	3
WEIGHT DECREASED			
subjects affected / exposed	9 / 63 (14.29%)	4 / 63 (6.35%)	8 / 63 (12.70%)
occurrences (all)	9	4	8
Injury, poisoning and procedural complications			
CONTUSION			
subjects affected / exposed	14 / 63 (22.22%)	23 / 63 (36.51%)	22 / 63 (34.92%)
occurrences (all)	53	34	37
FALL			
subjects affected / exposed	47 / 63 (74.60%)	55 / 63 (87.30%)	54 / 63 (85.71%)
occurrences (all)	281	286	294
FOOT FRACTURE			
subjects affected / exposed	3 / 63 (4.76%)	3 / 63 (4.76%)	4 / 63 (6.35%)
occurrences (all)	3	4	4
HEAD INJURY			
subjects affected / exposed	4 / 63 (6.35%)	4 / 63 (6.35%)	3 / 63 (4.76%)
occurrences (all)	4	4	3
INJURY			

subjects affected / exposed	4 / 63 (6.35%)	0 / 63 (0.00%)	7 / 63 (11.11%)
occurrences (all)	8	0	9
JOINT INJURY			
subjects affected / exposed	5 / 63 (7.94%)	3 / 63 (4.76%)	6 / 63 (9.52%)
occurrences (all)	13	4	6
LACERATION			
subjects affected / exposed	6 / 63 (9.52%)	5 / 63 (7.94%)	12 / 63 (19.05%)
occurrences (all)	7	5	14
LIGAMENT SPRAIN			
subjects affected / exposed	7 / 63 (11.11%)	10 / 63 (15.87%)	9 / 63 (14.29%)
occurrences (all)	8	14	12
LIMB INJURY			
subjects affected / exposed	5 / 63 (7.94%)	7 / 63 (11.11%)	2 / 63 (3.17%)
occurrences (all)	6	10	3
SKIN ABRASION			
subjects affected / exposed	14 / 63 (22.22%)	14 / 63 (22.22%)	14 / 63 (22.22%)
occurrences (all)	28	16	23
SOFT TISSUE INJURY			
subjects affected / exposed	3 / 63 (4.76%)	5 / 63 (7.94%)	1 / 63 (1.59%)
occurrences (all)	3	13	3
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	6 / 63 (9.52%)	10 / 63 (15.87%)	6 / 63 (9.52%)
occurrences (all)	7	13	7
DYSGEUSIA			
subjects affected / exposed	5 / 63 (7.94%)	1 / 63 (1.59%)	0 / 63 (0.00%)
occurrences (all)	5	1	0
HEADACHE			
subjects affected / exposed	12 / 63 (19.05%)	4 / 63 (6.35%)	14 / 63 (22.22%)
occurrences (all)	21	7	23
HYPOAESTHESIA			
subjects affected / exposed	2 / 63 (3.17%)	1 / 63 (1.59%)	3 / 63 (4.76%)
occurrences (all)	2	1	3
MUSCLE CONTRACTIONS INVOLUNTARY			

subjects affected / exposed	3 / 63 (4.76%)	6 / 63 (9.52%)	0 / 63 (0.00%)
occurrences (all)	3	7	0
PARAESTHESIA			
subjects affected / exposed	0 / 63 (0.00%)	2 / 63 (3.17%)	2 / 63 (3.17%)
occurrences (all)	0	2	2
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	5 / 63 (7.94%)	3 / 63 (4.76%)	0 / 63 (0.00%)
occurrences (all)	5	3	0
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	3 / 63 (4.76%)	4 / 63 (6.35%)	0 / 63 (0.00%)
occurrences (all)	3	5	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	2 / 63 (3.17%)	6 / 63 (9.52%)	1 / 63 (1.59%)
occurrences (all)	3	8	1
CONSTIPATION			
subjects affected / exposed	6 / 63 (9.52%)	3 / 63 (4.76%)	6 / 63 (9.52%)
occurrences (all)	6	3	6
DIARRHOEA			
subjects affected / exposed	32 / 63 (50.79%)	28 / 63 (44.44%)	20 / 63 (31.75%)
occurrences (all)	56	65	50
DRY MOUTH			
subjects affected / exposed	5 / 63 (7.94%)	1 / 63 (1.59%)	3 / 63 (4.76%)
occurrences (all)	5	1	4
DYSPHAGIA			
subjects affected / exposed	5 / 63 (7.94%)	4 / 63 (6.35%)	1 / 63 (1.59%)
occurrences (all)	6	4	1
NAUSEA			
subjects affected / exposed	11 / 63 (17.46%)	4 / 63 (6.35%)	9 / 63 (14.29%)
occurrences (all)	13	5	11
VOMITING			
subjects affected / exposed	4 / 63 (6.35%)	1 / 63 (1.59%)	2 / 63 (3.17%)
occurrences (all)	4	1	2
Skin and subcutaneous tissue disorders			

ACNE			
subjects affected / exposed	12 / 63 (19.05%)	19 / 63 (30.16%)	8 / 63 (12.70%)
occurrences (all)	15	33	10
DRY SKIN			
subjects affected / exposed	1 / 63 (1.59%)	2 / 63 (3.17%)	1 / 63 (1.59%)
occurrences (all)	1	2	1
PRURITUS			
subjects affected / exposed	6 / 63 (9.52%)	6 / 63 (9.52%)	6 / 63 (9.52%)
occurrences (all)	7	6	6
RASH			
subjects affected / exposed	13 / 63 (20.63%)	8 / 63 (12.70%)	9 / 63 (14.29%)
occurrences (all)	17	15	10
ROSACEA			
subjects affected / exposed	0 / 63 (0.00%)	4 / 63 (6.35%)	0 / 63 (0.00%)
occurrences (all)	0	7	0
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	15 / 63 (23.81%)	14 / 63 (22.22%)	19 / 63 (30.16%)
occurrences (all)	20	24	36
BACK PAIN			
subjects affected / exposed	10 / 63 (15.87%)	8 / 63 (12.70%)	14 / 63 (22.22%)
occurrences (all)	10	8	17
JOINT SWELLING			
subjects affected / exposed	5 / 63 (7.94%)	4 / 63 (6.35%)	1 / 63 (1.59%)
occurrences (all)	6	4	2
MUSCLE SPASMS			
subjects affected / exposed	32 / 63 (50.79%)	43 / 63 (68.25%)	25 / 63 (39.68%)
occurrences (all)	54	69	33
MUSCLE TWITCHING			
subjects affected / exposed	2 / 63 (3.17%)	4 / 63 (6.35%)	2 / 63 (3.17%)
occurrences (all)	3	6	2
MUSCULAR WEAKNESS			
subjects affected / exposed	2 / 63 (3.17%)	4 / 63 (6.35%)	3 / 63 (4.76%)
occurrences (all)	2	4	3
MUSCULOSKELETAL PAIN			

subjects affected / exposed	5 / 63 (7.94%)	4 / 63 (6.35%)	7 / 63 (11.11%)
occurrences (all)	5	5	10
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	4 / 63 (6.35%)	0 / 63 (0.00%)	1 / 63 (1.59%)
occurrences (all)	5	0	1
MYALGIA			
subjects affected / exposed	5 / 63 (7.94%)	11 / 63 (17.46%)	7 / 63 (11.11%)
occurrences (all)	5	13	10
PAIN IN EXTREMITY			
subjects affected / exposed	5 / 63 (7.94%)	4 / 63 (6.35%)	13 / 63 (20.63%)
occurrences (all)	5	5	26
Infections and infestations			
FOLLICULITIS			
subjects affected / exposed	4 / 63 (6.35%)	2 / 63 (3.17%)	0 / 63 (0.00%)
occurrences (all)	4	2	0
INFLUENZA			
subjects affected / exposed	2 / 63 (3.17%)	4 / 63 (6.35%)	4 / 63 (6.35%)
occurrences (all)	3	5	4
NASOPHARYNGITIS			
subjects affected / exposed	6 / 63 (9.52%)	11 / 63 (17.46%)	9 / 63 (14.29%)
occurrences (all)	8	11	13
RHINITIS			
subjects affected / exposed	0 / 63 (0.00%)	1 / 63 (1.59%)	1 / 63 (1.59%)
occurrences (all)	0	2	1
SINUSITIS			
subjects affected / exposed	1 / 63 (1.59%)	4 / 63 (6.35%)	1 / 63 (1.59%)
occurrences (all)	3	4	1
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	11 / 63 (17.46%)	11 / 63 (17.46%)	14 / 63 (22.22%)
occurrences (all)	13	14	19
URINARY TRACT INFECTION			
subjects affected / exposed	4 / 63 (6.35%)	4 / 63 (6.35%)	2 / 63 (3.17%)
occurrences (all)	4	7	4
Metabolism and nutrition disorders			

DECREASED APPETITE			
subjects affected / exposed	10 / 63 (15.87%)	3 / 63 (4.76%)	3 / 63 (4.76%)
occurrences (all)	10	3	3
GOUT			
subjects affected / exposed	3 / 63 (4.76%)	0 / 63 (0.00%)	4 / 63 (6.35%)
occurrences (all)	3	0	6
HYPERCHOLESTEROLAEMIA			
subjects affected / exposed	2 / 63 (3.17%)	4 / 63 (6.35%)	2 / 63 (3.17%)
occurrences (all)	2	4	2
HYPOMAGNESAEMIA			
subjects affected / exposed	4 / 63 (6.35%)	2 / 63 (3.17%)	0 / 63 (0.00%)
occurrences (all)	4	2	0
VITAMIN D DEFICIENCY			
subjects affected / exposed	6 / 63 (9.52%)	12 / 63 (19.05%)	3 / 63 (4.76%)
occurrences (all)	7	13	3

Non-serious adverse events	Placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	61 / 62 (98.39%)		
Vascular disorders			
HAEMATOMA			
subjects affected / exposed	2 / 62 (3.23%)		
occurrences (all)	3		
HYPERTENSION			
subjects affected / exposed	9 / 62 (14.52%)		
occurrences (all)	12		
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	6 / 62 (9.68%)		
occurrences (all)	6		
FATIGUE			
subjects affected / exposed	7 / 62 (11.29%)		
occurrences (all)	8		
OEDEMA PERIPHERAL			
subjects affected / exposed	7 / 62 (11.29%)		
occurrences (all)	8		
PYREXIA			

subjects affected / exposed	5 / 62 (8.06%)		
occurrences (all)	16		
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	8 / 62 (12.90%)		
occurrences (all)	10		
DYSPNOEA			
subjects affected / exposed	4 / 62 (6.45%)		
occurrences (all)	4		
RHINORRHOEA			
subjects affected / exposed	5 / 62 (8.06%)		
occurrences (all)	5		
Psychiatric disorders			
ANXIETY			
subjects affected / exposed	2 / 62 (3.23%)		
occurrences (all)	2		
DEPRESSED MOOD			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
DEPRESSION			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
INSOMNIA			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
Investigations			
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
VITAMIN D DECREASED			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
WEIGHT DECREASED			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	3		
Injury, poisoning and procedural			

complications			
CONTUSION			
subjects affected / exposed	22 / 62 (35.48%)		
occurrences (all)	34		
FALL			
subjects affected / exposed	52 / 62 (83.87%)		
occurrences (all)	356		
FOOT FRACTURE			
subjects affected / exposed	4 / 62 (6.45%)		
occurrences (all)	4		
HEAD INJURY			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	6		
INJURY			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	4		
JOINT INJURY			
subjects affected / exposed	5 / 62 (8.06%)		
occurrences (all)	5		
LACERATION			
subjects affected / exposed	9 / 62 (14.52%)		
occurrences (all)	15		
LIGAMENT SPRAIN			
subjects affected / exposed	10 / 62 (16.13%)		
occurrences (all)	14		
LIMB INJURY			
subjects affected / exposed	8 / 62 (12.90%)		
occurrences (all)	10		
SKIN ABRASION			
subjects affected / exposed	17 / 62 (27.42%)		
occurrences (all)	35		
SOFT TISSUE INJURY			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	3		
Nervous system disorders			

DIZZINESS			
subjects affected / exposed	8 / 62 (12.90%)		
occurrences (all)	11		
DYSGEUSIA			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
HEADACHE			
subjects affected / exposed	9 / 62 (14.52%)		
occurrences (all)	15		
HYPOAESTHESIA			
subjects affected / exposed	5 / 62 (8.06%)		
occurrences (all)	6		
MUSCLE CONTRACTIONS INVOLUNTARY			
subjects affected / exposed	2 / 62 (3.23%)		
occurrences (all)	2		
PARAESTHESIA			
subjects affected / exposed	5 / 62 (8.06%)		
occurrences (all)	5		
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
Gastrointestinal disorders			
ABDOMINAL PAIN			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
CONSTIPATION			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	3		
DIARRHOEA			
subjects affected / exposed	11 / 62 (17.74%)		
occurrences (all)	30		
DRY MOUTH			

subjects affected / exposed	4 / 62 (6.45%)		
occurrences (all)	4		
DYSPHAGIA			
subjects affected / exposed	5 / 62 (8.06%)		
occurrences (all)	5		
NAUSEA			
subjects affected / exposed	5 / 62 (8.06%)		
occurrences (all)	5		
VOMITING			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	3		
Skin and subcutaneous tissue disorders			
ACNE			
subjects affected / exposed	6 / 62 (9.68%)		
occurrences (all)	6		
DRY SKIN			
subjects affected / exposed	5 / 62 (8.06%)		
occurrences (all)	5		
PRURITUS			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
RASH			
subjects affected / exposed	8 / 62 (12.90%)		
occurrences (all)	10		
ROSACEA			
subjects affected / exposed	0 / 62 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	15 / 62 (24.19%)		
occurrences (all)	29		
BACK PAIN			
subjects affected / exposed	9 / 62 (14.52%)		
occurrences (all)	13		
JOINT SWELLING			

subjects affected / exposed	6 / 62 (9.68%)		
occurrences (all)	6		
MUSCLE SPASMS			
subjects affected / exposed	13 / 62 (20.97%)		
occurrences (all)	17		
MUSCLE TWITCHING			
subjects affected / exposed	4 / 62 (6.45%)		
occurrences (all)	6		
MUSCULAR WEAKNESS			
subjects affected / exposed	3 / 62 (4.84%)		
occurrences (all)	3		
MUSCULOSKELETAL PAIN			
subjects affected / exposed	4 / 62 (6.45%)		
occurrences (all)	4		
MUSCULOSKELETAL STIFFNESS			
subjects affected / exposed	2 / 62 (3.23%)		
occurrences (all)	2		
MYALGIA			
subjects affected / exposed	8 / 62 (12.90%)		
occurrences (all)	12		
PAIN IN EXTREMITY			
subjects affected / exposed	7 / 62 (11.29%)		
occurrences (all)	9		
Infections and infestations			
FOLLICULITIS			
subjects affected / exposed	1 / 62 (1.61%)		
occurrences (all)	1		
INFLUENZA			
subjects affected / exposed	2 / 62 (3.23%)		
occurrences (all)	2		
NASOPHARYNGITIS			
subjects affected / exposed	6 / 62 (9.68%)		
occurrences (all)	6		
RHINITIS			
subjects affected / exposed	4 / 62 (6.45%)		
occurrences (all)	5		

SINUSITIS subjects affected / exposed occurrences (all)	4 / 62 (6.45%) 6		
UPPER RESPIRATORY TRACT INFECTION subjects affected / exposed occurrences (all)	10 / 62 (16.13%) 16		
URINARY TRACT INFECTION subjects affected / exposed occurrences (all)	4 / 62 (6.45%) 4		
Metabolism and nutrition disorders			
DECREASED APPETITE subjects affected / exposed occurrences (all)	1 / 62 (1.61%) 1		
GOUT subjects affected / exposed occurrences (all)	2 / 62 (3.23%) 5		
HYPERCHOLESTEROLAEMIA subjects affected / exposed occurrences (all)	1 / 62 (1.61%) 1		
HYPOMAGNESAEMIA subjects affected / exposed occurrences (all)	0 / 62 (0.00%) 0		
VITAMIN D DEFICIENCY subjects affected / exposed occurrences (all)	11 / 62 (17.74%) 12		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported