Clinical trial results:
A Phase IIB, Randomized, Double blinded, Placebo controlled, Parallel group Study to Evaluate the Efficacy and Safety of MEDI6570 in Participants with a Prior Myocardial Infarction, Persistent Inflammation, and Elevated N terminal Prohormone Brain Natriuretic Peptide

Summary

EudraCT number	2020-000840-75
Trial protocol	HU CZ PL NL IT
Global end of trial date	09 May 2024

Results information

Result version number	v2 (current)
This version publication date	14 May 2025
First version publication date	24 November 2024
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	D4920C00002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04610892
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AstraZeneca
Sponsor organisation address	AB, 151 85, Södertälje, Sweden,
Public contact	Global Clinical Lead, AstraZeneca, +1 8772409479, information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, AstraZeneca, +1 8772409479, information.center@astrazeneca.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	29 January 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 January 2024
Global end of trial reached?	Yes
Global end of trial date	09 May 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the effect of MEDI6570 on non-calcified coronary atherosclerotic plaques compared with placebo

Protection of trial subjects:

The DMC will be responsible for safeguarding the interests of the participants, by assessing the safety of the intervention during the study and for reviewing the overall conduct of the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 November 2020
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: 15
Country: Number of subjects enrolled	Canada: 4
Country: Number of subjects enrolled	Czechia: 54
Country: Number of subjects enrolled	Hungary: 55
Country: Number of subjects enrolled	Italy: 54
Country: Number of subjects enrolled	Japan: 32
Country: Number of subjects enrolled	Netherlands: 41
Country: Number of subjects enrolled	Poland: 40
Country: Number of subjects enrolled	Spain: 69
Country: Number of subjects enrolled	United Kingdom: 11
Country: Number of subjects enrolled	United States: 48
Worldwide total number of subjects	423
EEA total number of subjects	313

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)	285
From 65 to 84 years	138
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted between 4/11/2020 and 08/11/2023 in below countries.
Australia
Canada
Czech Republic
Hungary
Italy
Japan
Netherlands
Poland
Spain
United Kingdom
United States of America

Pre-assignment

Screening details:

Subjects who met the inclusion and none of the exclusion criteria were enrolled in the study. All study assessments were performed as per the schedule of assessment.

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

Arms

Are arms mutually exclusive?	Yes
Arm title	MEDI6570 50 mg

Arm description:

Participants received MEDI6570 50 mg every 4 weeks for 32 weeks

Arm type	Experimental
Investigational medicinal product name	MEDI6570
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 1 injection (0.5 mL) of MEDI6570 50 mg every 4 weeks for 32 weeks

Arm title	MEDI6570 150 mg

Arm description:

Participants received MEDI6570 150 mg every 4 weeks for 32 weeks

Arm type	Experimental
Investigational medicinal product name	MEDI6570
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received 1 injection (1.5 mL) of MEDI6570 150 mg every 4 weeks for 32 weeks

Arm title	MEDI6570 400 mg

Arm description:	
Participants received MEDI6570 400 mg every 4 weeks for 32 weeks. 8 participants initially randomized to 250 mg that switched dose to 400 mg during the trial.	
Arm type	Experimental
Investigational medicinal product name	MEDI6570
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Participants received 2 injections (2 mL per injection) of MEDI6570 400 mg every 4 weeks for 32 weeks	
Arm title	Placebo
Arm description:	
Participants received Placebo matched to MEDI6570 every 4 weeks for 32 weeks	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use
Dosage and administration details:	
Participants received injection (s) of matched placebo every 4 weeks for 32 weeks	

Number of subjects in period 1	MEDI6570 50 mg	MEDI6570 150 mg	MEDI6570 400 mg
Started	40	129	126
Completed	35	126	118
Not completed	5	3	8
Adverse event, serious fatal	-	1	1
Consent withdrawn by subject	3	2	6
Adverse event, non-fatal	1	-	1
Subjects who did not receive treatment	1	-	-

Number of subjects in period 1	Placebo
Started	128
Completed	117
Not completed	11
Adverse event, serious fatal	-
Consent withdrawn by subject	6
Adverse event, non-fatal	3
Subjects who did not receive treatment	2

Baseline characteristics

Reporting groups	
Reporting group title	MEDI6570 50 mg
Reporting group description:	
Participants received MEDI6570 50 mg every 4 weeks for 32 weeks	
Reporting group title	MEDI6570 150 mg
Reporting group description:	
Participants received MEDI6570 150 mg every 4 weeks for 32 weeks	
Reporting group title	MEDI6570 400 mg
Reporting group description:	
Participants received MEDI6570 400 mg every 4 weeks for 32 weeks. 8 participants initially randomized to 250 mg that switched dose to 400 mg during the trial.	
Reporting group title	Placebo
Reporting group description:	
Participants received Placebo matched to MEDI6570 every 4 weeks for 32 weeks	

Reporting group values	MEDI6570 50 mg	MEDI6570 150 mg	MEDI6570 400 mg
Number of subjects	40	129	126
Age categorical Units: Subjects			
≥ 21 to < 40 years	0	1	1
≥ 40 to < 50 years	4	18	21
≥ 50 to < 65 years	25	66	64
≥ 65 years	11	44	40
Age Continuous Units: Years			
arithmetic mean	60.1	59.9	59.4
standard deviation	± 8.3	± 9.2	± 9.6
Sex: Female, Male Units: Participants			
Female	12	19	23
Male	28	110	103
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	5	5	2
Not Hispanic or Latino	35	124	124
Unknown	0	0	0
Race (NIH/OMB) Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	0	0	0
ASIAN	7	10	8
BLACK OR AFRICAN AMERICAN	0	1	0
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	1	0
OTHER	0	1	0
WHITE	33	116	118
Region of Enrollment Units: Subjects			

Australia	0	6	6
Canada	0	3	1
Czech Republic	2	17	17
Hungary	9	11	12
Italy	0	14	21
Japan	7	9	8
Netherlands	1	18	11
Poland	2	14	14
Spain	13	20	18
United Kingdom	0	5	5
United States of America	6	12	13
Race/Ethnicity, Customized Units: Subjects			
Caucasian	33	116	118
Non-caucasian	7	13	8
Missing	0	0	0

Reporting group values	Placebo	Total	
Number of subjects	128	423	
Age categorical Units: Subjects			
≥ 21 to < 40 years	0	2	
≥ 40 to < 50 years	17	60	
≥ 50 to < 65 years	68	223	
≥ 65 years	43	138	
Age Continuous Units: Years			
arithmetic mean	60.4		
standard deviation	± 9.5	-	
Sex: Female, Male Units: Participants			
Female	21	75	
Male	107	348	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	7	19	
Not Hispanic or Latino	121	404	
Unknown	0	0	
Race (NIH/OMB) Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	1	1	
ASIAN	9	34	
BLACK OR AFRICAN AMERICAN	0	1	
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	1	
OTHER	0	1	
WHITE	118	385	
Region of Enrollment Units: Subjects			
Australia	3	15	
Canada	0	4	

Czech Republic	18	54	
Hungary	23	55	
Italy	19	54	
Japan	8	32	
Netherlands	11	41	
Poland	10	40	
Spain	18	69	
United Kingdom	1	11	
United States of America	17	48	
Race/Ethnicity, Customized Units: Subjects			
Caucasian	118	385	
Non-caucasian	10	38	
Missing	0	0	

End points

End points reporting groups	
Reporting group title	MEDI6570 50 mg
Reporting group description:	
Participants received MEDI6570 50 mg every 4 weeks for 32 weeks	
Reporting group title	MEDI6570 150 mg
Reporting group description:	
Participants received MEDI6570 150 mg every 4 weeks for 32 weeks	
Reporting group title	MEDI6570 400 mg
Reporting group description:	
Participants received MEDI6570 400 mg every 4 weeks for 32 weeks. 8 participants initially randomized to 250 mg that switched dose to 400 mg during the trial.	
Reporting group title	Placebo
Reporting group description:	
Participants received Placebo matched to MEDI6570 every 4 weeks for 32 weeks	
Subject analysis set title	MEDI6570 150 mg or 400 mg
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
This group was added only for statistical modelling	

Primary: Change from baseline to Day 253 in non-calcified plaque volume in the most diseased coronary segment (NCPVMD), as measured by Computed Tomography Angiography (CTA) imaging

End point title	Change from baseline to Day 253 in non-calcified plaque volume in the most diseased coronary segment (NCPVMD), as measured by Computed Tomography Angiography (CTA) imaging
End point description:	
To evaluate the effect of MEDI6570 on non-calcified coronary atherosclerotic plaques compared with placebo. The primary endpoint of change in NCPVMD from baseline to Day 253 was assessed based on the CTA Analysis Populations.	
End point type	Primary
End point timeframe:	
From baseline to Day 253	

End point values	MEDI6570 50 mg	MEDI6570 150 mg	MEDI6570 400 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	125	116	117
Units: mm3				
least squares mean (standard error)	-15.3220 (± 4.9219)	-4.5509 (± 3.1654)	-6.3658 (± 3.2559)	-6.9424 (± 3.2729)

End point values	MEDI6570 150 mg or 400 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	245[1]			

Units: mm3				
least squares mean (standard error)	-5.4220 (± 2.6622)			

Notes:

[1] - NCPVMD analysis is based on the CTA analysis population, a subset of the ITT Population.

Statistical analyses

Statistical analysis title	Comparing groups: MEDI6570 50 mg vs Placebo
Comparison groups	MEDI6570 50 mg v Placebo
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.065 [2]
Method	ANCOVA
Parameter estimate	Least Square Mean difference
Point estimate	-8.3797
Confidence interval	
level	90 %
sides	2-sided
lower limit	-17.498
upper limit	0.7387

Notes:

[2] - One-sided p-value

Statistical analysis title	MEDI6570 150 mg or 400 mg vs Placebo
Comparison groups	Placebo v MEDI6570 150 mg or 400 mg
Number of subjects included in analysis	362
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.685 [3]
Method	ANCOVA
Parameter estimate	Least Square Mean difference
Point estimate	1.5204
Confidence interval	
level	90 %
sides	2-sided
lower limit	-3.6657
upper limit	6.7064

Notes:

[3] - One-sided p-value

Statistical analysis title	Comparing groups: MEDI6570 400 mg vs Placebo
Comparison groups	MEDI6570 400 mg v Placebo

Number of subjects included in analysis	233
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.563 [4]
Method	ANCOVA
Parameter estimate	Least Square Mean difference
Point estimate	0.5766
Confidence interval	
level	90 %
sides	2-sided
lower limit	-5.4389
upper limit	6.5921

Notes:

[4] - One-sided p-value

Statistical analysis title	Comparing groups: MEDI6570 150 mg vs Placebo
Comparison groups	MEDI6570 150 mg v Placebo
Number of subjects included in analysis	242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.747 [5]
Method	ANCOVA
Parameter estimate	Least Square Mean difference
Point estimate	2.3915
Confidence interval	
level	90 %
sides	2-sided
lower limit	-3.5338
upper limit	8.3167

Notes:

[5] - One-sided p-value

Secondary: Change from baseline to Day 253 in N Terminal Prohormone Brain Natriuretic Peptide (NT-proBNP)

End point title	Change from baseline to Day 253 in N Terminal Prohormone Brain Natriuretic Peptide (NT-proBNP)

End point description:

To evaluate the effect of MEDI6570 on a surrogate biomarker of HF compared with placebo

End point type	Secondary

End point timeframe:

From baseline to Day 253

End point values	MEDI6570 50 mg	MEDI6570 150 mg	MEDI6570 400 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	125	123	118
Units: pg/mL				
geometric mean (geometric coefficient of variation)	0.8226 (± 9.4)	0.7787 (± 5.5)	0.7368 (± 5.6)	0.7370 (± 5.6)

End point values	MEDI6570 150 mg or 400 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	248			
Units: pg/mL				
geometric mean (geometric coefficient of variation)	0.7575 (± 4.4)			

Statistical analyses

Statistical analysis title	Comparing groups: MEDI6570 50 mg vs Placebo
Comparison groups	MEDI6570 50 mg v Placebo
Number of subjects included in analysis	153
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.854 [6]
Method	Mixed model with repeated measurements
Parameter estimate	Geometric LS mean ratio estimate
Point estimate	1.12
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.94
upper limit	1.33

Notes:

[6] - One sided p-value

Statistical analysis title	MEDI6570 150 mg or 400 mg vs Placebo
Comparison groups	Placebo v MEDI6570 150 mg or 400 mg
Number of subjects included in analysis	366
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.678 [7]
Method	Mixed model with repeated measurements
Parameter estimate	Geometric LS mean ratio estimate
Point estimate	1.03

Confidence interval	
level	90 %
sides	2-sided
lower limit	0.93
upper limit	1.13

Notes:

[7] - One sided p-value

Statistical analysis title	Comparing groups: MEDI6570 400 mg vs Placebo
Comparison groups	MEDI6570 400 mg v Placebo
Number of subjects included in analysis	241
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.498 [8]
Method	Mixed model with repeated measurements
Parameter estimate	Geometric LS mean ratio estimate
Point estimate	1
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.89
upper limit	1.12

Notes:

[8] - One sided p-value

Statistical analysis title	Comparing groups: MEDI6570 150 mg vs Placebo
Comparison groups	MEDI6570 150 mg v Placebo
Number of subjects included in analysis	243
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.79 [9]
Method	Mixed model with repeated measurements
Parameter estimate	Geometric LS mean ratio estimate
Point estimate	1.06
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.94
upper limit	1.18

Notes:

[9] - One sided p-value

Secondary: Change from baseline to Day 253 in Left Ventricular Ejection Fraction (LVEF)

End point title	Change from baseline to Day 253 in Left Ventricular Ejection Fraction (LVEF)

End point description:

To evaluate the effect of MEDI6570 on left ventricular systolic function compared with placebo

End point type	Secondary

End point timeframe:
From baseline to Day 253

End point values	MEDI6570 50 mg	MEDI6570 150 mg	MEDI6570 400 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	115	112	103
Units: Percentage				
least squares mean (standard error)	-0.91 (± 0.55)	0.32 (± 0.34)	0.11 (± 0.35)	0.53 (± 0.35)

End point values	MEDI6570 150 mg or 400 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	227[10]			
Units: Percentage				
least squares mean (standard error)	0.22 (± 0.28)			

Notes:
[10] - LVEF analysis was based on the Echocardiogram analysis population, a subset of ITT population.

Statistical analyses

Statistical analysis title	Comparing groups: MEDI6570 50 mg vs Placebo
Comparison groups	MEDI6570 50 mg v Placebo
Number of subjects included in analysis	134
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.99 [11]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-1.44
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.44
upper limit	-0.43

Notes:
[11] - One sided p-value

Statistical analysis title	Comparing groups: MEDI6570 150 mg vs Placebo
Comparison groups	MEDI6570 150 mg v Placebo

Number of subjects included in analysis	218
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.697 [12]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-0.21
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.87
upper limit	0.45

Notes:

[12] - One sided p-value

Statistical analysis title	Comparing groups: MEDI6570 400 mg vs Placebo
Comparison groups	MEDI6570 400 mg v Placebo
Number of subjects included in analysis	215
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.849 [13]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-0.42
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.08
upper limit	0.25

Notes:

[13] - One sided p-value

Statistical analysis title	MEDI6570 150 mg or 400 mg vs Placebo
Comparison groups	Placebo v MEDI6570 150 mg or 400 mg
Number of subjects included in analysis	330
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.811
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-0.31
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.89
upper limit	0.27

Secondary: Left ventricular ejection fraction (LVEF) change from baseline to Day

253 among subjects with reduced ejection fraction (< 50%)	
End point title	Left ventricular ejection fraction (LVEF) change from baseline to Day 253 among subjects with reduced ejection fraction (< 50%)

End point description:

To evaluate the effect of MEDI6570 on left ventricular systolic function among participants with reduced ejection fraction (defined as <50%) compared with placebo

End point type	Secondary

End point timeframe:

From baseline to Day 253

End point values	MEDI6570 50 mg	MEDI6570 150 mg	MEDI6570 400 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	13	20	14
Units: Percentage				
least squares mean (standard error)	-1.08 (± 1.52)	1.32 (± 1.13)	2.09 (± 1.00)	2.41 (± 1.04)

End point values	MEDI6570 150 mg or 400 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	33[14]			
Units: Percentage				
least squares mean (standard error)	1.79 (± 0.82)			

Notes:

[14] - LVEF analysis was based on the Echocardiogram analysis population, a sub set of ITT population.

Statistical analyses

Statistical analysis title	Comparing groups: MEDI6570 50 mg vs Placebo
Comparison groups	MEDI6570 50 mg v Placebo
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.972 [15]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-3.5
Confidence interval	
level	90 %
sides	2-sided
lower limit	-6.49
upper limit	-0.5

Notes:
[15] - One sided p-value

Statistical analysis title	MEDI6570 150 mg or 400 mg vs Placebo
Comparison groups	Placebo v MEDI6570 150 mg or 400 mg
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.698
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-0.63
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.64
upper limit	1.38

Statistical analysis title	Comparing groups: MEDI6570 400 mg vs Placebo
Comparison groups	MEDI6570 400 mg v Placebo
Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.596 [16]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-0.32
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.54
upper limit	1.89

Notes:
[16] - One sided p-value

Statistical analysis title	Comparing groups: MEDI6570 150 mg vs Placebo
Comparison groups	MEDI6570 150 mg v Placebo
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.777 [17]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-1.1

Confidence interval	
level	90 %
sides	2-sided
lower limit	-3.49
upper limit	1.3

Notes:

[17] - One sided p-value

Secondary: Change from baseline to Day 253 in Global Longitudinal Strain (GLS)

End point title	Change from baseline to Day 253 in Global Longitudinal Strain (GLS)

End point description:

To evaluate the effect of MEDI6570 on left ventricular systolic function compared with placebo

End point type	Secondary

End point timeframe:

From baseline to Day 253

End point values	MEDI6570 50 mg	MEDI6570 150 mg	MEDI6570 400 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	29	105	109	100
Units: Percentage				
least squares mean (standard error)	-1.20 (± 0.56)	-0.70 (± 0.35)	-0.77 (± 0.35)	0.09 (± 0.35)

End point values	MEDI6570 150 mg or 400 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	214[18]			
Units: Percentage				
least squares mean (standard error)	-0.74 (± 0.29)			

Notes:

[18] - GLS analysis is based on the Echocardiogram analysis population, a subset of ITT population.

Statistical analyses

Statistical analysis title	Comparing groups: MEDI6570 50 mg vs Placebo
Comparison groups	MEDI6570 50 mg v Placebo
Number of subjects included in analysis	129
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.981 [19]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-1.29

Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.32
upper limit	-0.27

Notes:

[19] - One sided p-value

Statistical analysis title	Comparing groups: MEDI6570 400 mg vs Placebo
Comparison groups	MEDI6570 400 mg v Placebo
Number of subjects included in analysis	209
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.983 [20]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-0.86
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.53
upper limit	-0.2

Notes:

[20] - One sided p-value

Statistical analysis title	MEDI6570 150 mg or 400 mg vs Placebo
Comparison groups	Placebo v MEDI6570 150 mg or 400 mg
Number of subjects included in analysis	314
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.99
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-0.83
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.42
upper limit	-0.25

Statistical analysis title	Comparing groups: MEDI6570 150 mg vs Placebo
Comparison groups	MEDI6570 150 mg v Placebo

Number of subjects included in analysis	205
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.974 [21]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-0.8
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.47
upper limit	-0.12

Notes:

[21] - One sided p-value

Secondary: Global longitudinal strain (GLS) change from baseline to Day 253 among subjects with reduced ejection fraction (< 50%)

End point title	Global longitudinal strain (GLS) change from baseline to Day 253 among subjects with reduced ejection fraction (< 50%)

End point description:

To evaluate the effect of MEDI6570 on left ventricular systolic function among participants with reduced ejection fraction (defined as <50%) compared with placebo

End point type	Secondary

End point timeframe:

From baseline to Day 253

End point values	MEDI6570 50 mg	MEDI6570 150 mg	MEDI6570 400 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	12	20	15
Units: Percentage				
least squares mean (standard error)	-0.39 (± 1.03)	-1.16 (± 0.78)	0.41 (± 0.64)	1.76 (± 0.66)

End point values	MEDI6570 150 mg or 400 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	32[22]			
Units: Percentage				
least squares mean (standard error)	-0.19 (± 0.55)			

Notes:

[22] - GLS analysis is based on the Echocardiogram analysis population, a subset of ITT population.

Statistical analyses

Statistical analysis title	Comparing groups: MEDI6570 50 mg vs Placebo
Comparison groups	MEDI6570 50 mg v Placebo
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.959 [23]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-2.14
Confidence interval	
level	90 %
sides	2-sided
lower limit	-4.16
upper limit	-0.12

Notes:

[23] - One sided p-value

Statistical analysis title	MEDI6570 150 mg or 400 mg vs Placebo
Comparison groups	Placebo v MEDI6570 150 mg or 400 mg
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.991
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-1.94
Confidence interval	
level	90 %
sides	2-sided
lower limit	-3.27
upper limit	-0.62

Statistical analysis title	Comparing groups: MEDI6570 400 mg vs Placebo
Comparison groups	MEDI6570 400 mg v Placebo
Number of subjects included in analysis	35
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.939 [24]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-1.35
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.79
upper limit	0.09

Notes:
[24] - One sided p-value

Statistical analysis title	Comparing groups: MEDI6570 150 mg vs Placebo
Comparison groups	MEDI6570 150 mg v Placebo
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.998 [25]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-2.92
Confidence interval	
level	90 %
sides	2-sided
lower limit	-4.53
upper limit	-1.31

Notes:
[25] - One sided p-value

Secondary: Change from baseline to Day 253 in Global non-calcified plaque volume (NCPV)

End point title	Change from baseline to Day 253 in Global non-calcified plaque volume (NCPV)

End point description:

To evaluate the effect of MEDI6570 on other measures of non-calcified coronary atherosclerotic plaque compared with placebo

End point type	Secondary

End point timeframe:

From baseline to Day 253

End point values	MEDI6570 50 mg	MEDI6570 150 mg	MEDI6570 400 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	125	116	117
Units: mm3				
least squares mean (standard error)	-26.4453 (± 10.0524)	-10.9010 (± 6.4671)	-10.4850 (± 6.6607)	-10.3083 (± 6.7052)

End point values	MEDI6570 150 mg or 400 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	241[26]			
Units: mm3				
least squares mean (standard error)	-10.7013 (± 5.4415)			

Notes:
[26] - NCPV analysis is based on the CTA analysis population, a subset of ITT population.

Statistical analyses

Statistical analysis title	Comparing groups: MEDI6570 50 mg vs Placebo
Comparison groups	MEDI6570 50 mg v Placebo
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.077 [27]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-16.137
Confidence interval	
level	90 %
sides	2-sided
lower limit	-34.7829
upper limit	2.5089

Notes:
[27] - One sided p-value

Statistical analysis title	MEDI6570 150 mg or 400 mg vs Placebo
Comparison groups	Placebo v MEDI6570 150 mg or 400 mg
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.476
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-0.393
Confidence interval	
level	90 %
sides	2-sided
lower limit	-11.0022
upper limit	10.2162

Statistical analysis title	Comparing groups: MEDI6570 400 mg vs Placebo
Comparison groups	MEDI6570 400 mg v Placebo

Number of subjects included in analysis	233
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.491 [28]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-0.1767
Confidence interval	
level	90 %
sides	2-sided
lower limit	-12.4678
upper limit	12.1144

Notes:

[28] - One sided p-value

Statistical analysis title	Comparing groups: MEDI6570 150 mg vs Placebo
Comparison groups	MEDI6570 150 mg v Placebo
Number of subjects included in analysis	242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.468 [29]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-0.5927
Confidence interval	
level	90 %
sides	2-sided
lower limit	-12.7267
upper limit	11.5413

Notes:

[29] - One sided p-value

Secondary: Change from baseline to Day 253 in Low attenuation plaque volume (LAPV)

End point title	Change from baseline to Day 253 in Low attenuation plaque volume (LAPV)

End point description:

To evaluate the effect of MEDI6570 on other measures of non-calcified coronary atherosclerotic plaque compared with placebo

End point type	Secondary

End point timeframe:

From baseline to Day 253

End point values	MEDI6570 50 mg	MEDI6570 150 mg	MEDI6570 400 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	125	116	117
Units: mm3				
least squares mean (standard error)	-7.9167 (± 3.5226)	-4.8101 (± 2.2690)	-4.2748 (± 2.3363)	-3.5733 (± 2.3481)

End point values	MEDI6570 150 mg or 400 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	241[30]			
Units: mm3				
least squares mean (standard error)	-4.5532 (± 1.9099)			

Notes:

[30] - LAPV analysis is based on the CTA analysis population, a subset of ITT population.

Statistical analyses

Statistical analysis title	Comparing groups: MEDI6570 50 mg vs Placebo
Comparison groups	MEDI6570 50 mg v Placebo
Number of subjects included in analysis	151
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.136 [31]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-4.3435
Confidence interval	
level	90 %
sides	2-sided
lower limit	-10.8637
upper limit	2.1768

Notes:

[31] - One sided p-value

Statistical analysis title	Comparing groups: MEDI6570 150 mg vs Placebo
Comparison groups	MEDI6570 150 mg v Placebo
Number of subjects included in analysis	242
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.316 [32]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-1.2369

Confidence interval	
level	90 %
sides	2-sided
lower limit	-5.4796
upper limit	3.0059

Notes:

[32] - One sided p-value

Statistical analysis title	Comparing groups: MEDI6570 400 mg vs Placebo
Comparison groups	MEDI6570 400 mg v Placebo
Number of subjects included in analysis	233
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.394 [33]
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-0.7015
Confidence interval	
level	90 %
sides	2-sided
lower limit	-5.0096
upper limit	3.6065

Notes:

[33] - One sided p-value

Statistical analysis title	MEDI6570 150 mg or 400 mg vs Placebo
Comparison groups	Placebo v MEDI6570 150 mg or 400 mg
Number of subjects included in analysis	358
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.332
Method	ANCOVA
Parameter estimate	Least Squares mean difference
Point estimate	-0.9799
Confidence interval	
level	90 %
sides	2-sided
lower limit	-4.6927
upper limit	2.7329

Secondary: Summary of ADA Responses During the Study

End point title	Summary of ADA Responses During the Study

End point description:

To evaluate the immunogenicity of MEDI6570

End point type	Secondary

End point timeframe:

From baseline to end of the study

End point values	MEDI6570 50 mg	MEDI6570 150 mg	MEDI6570 400 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	129	126	126
Units: Participants				
ADA prevalence(positive at baseline/post-baseline)	2	10	3	1
ADA incidence (TEADA positive)	2	9	2	1
Treatment-induced ADA positive	2	9	2	1
Treatment-boosted ADA positive	0	1	0	0
ADA persistently positive	2	7	1	1

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-drug antibody Titre summary by visit

End point title	Anti-drug antibody Titre summary by visit
End point description:	
To evaluate the immunogenicity of MEDI6570	
End point type	Secondary
End point timeframe:	
From Baseline to Day 325/405	

End point values	MEDI6570 50 mg	MEDI6570 150 mg	MEDI6570 400 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	129	126	126
Units: Titer units				
median (full range (min-max))				
Baseline	0 (0 to 0)	80 (80 to 80)	320 (320 to 320)	0 (0 to 0)
Day 29	0 (0 to 0)	640 (640 to 640)	0 (0 to 0)	0 (0 to 0)
Day 57	0 (0 to 0)	80 (80 to 80)	0 (0 to 0)	0 (0 to 0)
Day 113	640 (640 to 640)	640 (640 to 640)	0 (0 to 0)	0 (0 to 0)
Day 169	320 (320 to 320)	1600 (640 to 2560)	0 (0 to 0)	0 (0 to 0)
Day 253	160 (160 to 160)	1360 (160 to 2560)	80 (80 to 80)	0 (0 to 0)
Day 325/405	120.0 (80 to 160)	320 (80 to 1280)	80 (80 to 80)	0 (0 to 0)

Statistical analyses

No statistical analyses for this end point

Secondary: Summary of serum concentrations (ug/mL) of MEDI6570

End point title	Summary of serum concentrations (ug/mL) of MEDI6570[34]

End point description:

MEDI6570 concentrations as measured in serum during the intervention and follow-up periods

End point type	Secondary

End point timeframe:

From baseline to Day 325/Day 405

Notes:

[34] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: We are not reporting serum concentration for placebo.

End point values	MEDI6570 50 mg	MEDI6570 150 mg	MEDI6570 400 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	38	129	117	
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Baseline (enter zero for values below LLOQ)	0 (± 0)	0 (± 0)	0 (± 0)	
Day 10	2.3126 (± 101.5)	7.0296 (± 125.9)	20.4472 (± 37.2)	
Day 29	0.6154 (± 170.7)	3.4641 (± 103.2)	9.5328 (± 115.4)	
Day 57	0.7622 (± 235.5)	4.3897 (± 145.9)	15.0108 (± 50.3)	
Day 85	1.1353 (± 217.3)	6.4317 (± 62.0)	10.8714 (± 608.2)	
Day 113	1.0084 (± 176.7)	5.4403 (± 120.1)	15.5611 (± 77.1)	
Day 122	4.6703 (± 37.0)	8.1229 (± 792.0)	28.1805 (± 168.8)	
Day 141	1.4191 (± 129.5)	8.0736 (± 47.2)	10.4080 (± 647.5)	
Day 169	0.8016 (± 171.6)	5.2865 (± 163.4)	15.9449 (± 145.9)	
Day 197 (enter zero for values below LLOQ)	0 (± 0)	0 (± 0)	0 (± 0)	
Day 225 (enter zero for values below LLOQ)	2.2469 (± 86.3)	3.6384 (± 633.4)	0 (± 0)	
Day 253	0.7253 (± 288.4)	5.6832 (± 136.0)	14.9944 (± 173.4)	
Day 325/Day 405 (enter zero for values below LLOQ)	0 (± 0)	0 (± 0)	0.5955 (± 720.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Adverse Events in Any Category

End point title	Number of Participants with Adverse Events in Any Category

End point description:

To assess the safety and tolerability of MEDI6570 compared with placebo

End point type	Secondary

End point timeframe:

During study follow-up

End point values	MEDI6570 50 mg	MEDI6570 150 mg	MEDI6570 400 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	129	126	126
Units: participants				
Any AEs|n (%)	26	87	79	65
Any AEs with outcome of death|n (%)	0	1	1	0
Any SAE (including events with outcome of death)	4	17	10	13
Any AE leading to treatment discontinuation|n (%)	1	0	2	3
Any AE leading to withdrawal from study|n (%)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Most Common Adverse Events (Frequency > 5%)

End point title	Number of Participants with Most Common Adverse Events (Frequency > 5%)

End point description:

To assess the safety and tolerability of MEDI6570 compared with placebo

End point type	Secondary

End point timeframe:

During study follow-up

End point values	MEDI6570 50 mg	MEDI6570 150 mg	MEDI6570 400 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	129	126	126
Units: participants				
Participants with any AE|n (%)	16	35	38	26
COVID-19|n (%)	3	8	17	6
Hypertension|n (%)	2	4	9	9
Non-cardiac chest pain|n (%)	3	5	6	4
Dyspnoea|n (%)	2	3	4	3
Hypotension|n (%)	2	1	4	1
Angina pectoris|n (%)	2	10	3	6
Pyrexia|n (%)	2	1	3	1
Diarrhoea|n (%)	2	5	2	4
Epistaxis|n (%)	2	1	2	1
Influenza|n (%)	2	4	2	1
Nausea|n (%)	2	1	1	1
Pain in extremity|n (%)	2	1	1	1

Statistical analyses

No statistical analyses for this end point

Secondary: Vital signs and electrocardiogram (ECG) variables over time

End point title	Vital signs and electrocardiogram (ECG) variables over time

End point description:

To assess the safety and tolerability of MEDI6570 compared with placebo

End point type	Secondary

End point timeframe:

From baseline to Day 325/405

End point values	MEDI6570 50 mg	MEDI6570 150 mg	MEDI6570 400 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	129	126	126
Units: Unit vary for each Vital signs variable				
arithmetic mean (standard deviation)				
Systolic blood pressure (mmHg) Day 10	0.3 (± 9.9)	0.9 (± 12.7)	-1.4 (± 13.0)	0.4 (± 12.8)
Systolic blood pressure (mmHg) Day 29	-0.7 (± 10.8)	-1.1 (± 14.6)	-1.5 (± 11.9)	-1.3 (± 12.6)
Systolic blood pressure (mmHg) Day 57	1.4 (± 11.6)	0.7 (± 14.1)	-1.6 (± 12.3)	-0.1 (± 12.8)
Systolic blood pressure (mmHg) Day 85	0.7 (± 10.2)	1.5 (± 13.8)	-1.2 (± 12.7)	-0.5 (± 14.9)

Systolic blood pressure (mmHg) Day 113	-0.6 (± 10.6)	1.3 (± 15.2)	0.2 (± 13.7)	0.6 (± 13.1)
Systolic blood pressure (mmHg) Day 122	1.6 (± 16.4)	-4.0 (± 15.5)	-2.0 (± 13.8)	7.8 (± 17.1)
Systolic blood pressure (mmHg) Day 141	0.7 (± 15.0)	-0.2 (± 14.1)	-0.2 (± 14.1)	0.8 (± 13.3)
Systolic blood pressure (mmHg) Day 169	1.2 (± 13.4)	1.5 (± 12.5)	-0.3 (± 14.9)	0.5 (± 14.5)
Systolic blood pressure (mmHg) Day 197	0.7 (± 15.8)	0.6 (± 14.0)	-3.6 (± 13.5)	-0.4 (± 13.6)
Systolic blood pressure (mmHg) Day 225	2.8 (± 14.3)	1.7 (± 14.8)	-0.6 (± 15.1)	-0.3 (± 14.7)
Systolic blood pressure (mmHg) Day 253	-1.8 (± 15.5)	0.7 (± 14.4)	-0.9 (± 15.6)	0.2 (± 14.5)
Systolic blood pressure (mmHg) Day 325/405	-1.8 (± 12.8)	0.7 (± 14.1)	-2.5 (± 14.7)	0.1 (± 16.0)
Diastolic blood pressure (mmHg) Day 10	-0.2 (± 6.0)	0.6 (± 8.5)	-0.3 (± 8.4)	-0.4 (± 8.7)
Diastolic blood pressure (mmHg) Day 29	0.3 (± 8.5)	-1.3 (± 8.7)	-1.1 (± 9.7)	-1.3 (± 9.1)
Diastolic blood pressure (mmHg) Day 57	-1.1 (± 8.5)	-0.5 (± 8.4)	-0.9 (± 8.9)	-0.4 (± 8.5)
Diastolic blood pressure (mmHg) Day 85	-0.1 (± 9.0)	-0.5 (± 10.5)	-0.9 (± 8.9)	-0.6 (± 9.2)
Diastolic blood pressure (mmHg) Day 113	-0.3 (± 8.5)	0.1 (± 9.4)	-0.5 (± 8.9)	1.0 (± 9.1)
Diastolic blood pressure (mmHg) Day 122	-3.7 (± 10.4)	-3.9 (± 8.0)	-2.0 (± 7.5)	4.1 (± 12.3)
Diastolic blood pressure (mmHg) Day 141	-1.5 (± 8.4)	-1.1 (± 9.6)	-0.3 (± 8.5)	0.2 (± 7.9)
Diastolic blood pressure (mmHg) Day 169	-0.4 (± 9.5)	-0.3 (± 9.2)	-0.8 (± 9.0)	-0.4 (± 9.2)
Diastolic blood pressure (mmHg) Day 197	-1.6 (± 7.7)	0.0 (± 9.5)	-2.0 (± 9.8)	-0.3 (± 9.0)
Diastolic blood pressure (mmHg) Day 225	0.4 (± 9.5)	-1.6 (± 9.8)	-0.9 (± 8.8)	-0.8 (± 8.4)
Diastolic blood pressure (mmHg) Day 253	-3.7 (± 7.9)	-0.1 (± 10.7)	-1.0 (± 9.9)	-0.4 (± 9.3)
Diastolic blood pressure (mmHg) Day 325/405	-1.8 (± 8.5)	-0.5 (± 9.1)	-1.5 (± 10.3)	-0.7 (± 9.8)
Heart rate (beats/min) Day 10	0.4 (± 9.4)	0.6 (± 8.0)	0.4 (± 6.9)	-0.6 (± 8.6)
Heart rate (beats/min) Day 29	-0.5 (± 11.4)	0.7 (± 8.3)	1.3 (± 8.2)	-1.1 (± 8.5)
Heart rate (beats/min) Day 57	-2.1 (± 11.0)	0.9 (± 8.9)	2.5 (± 9.7)	1.1 (± 11.1)
Heart rate (beats/min) Day 85	-3.3 (± 9.4)	1.0 (± 9.2)	2.3 (± 8.3)	1.3 (± 10.4)
Heart rate (beats/min) Day 113	-1.8 (± 9.8)	0.5 (± 10.1)	0.2 (± 8.7)	0.2 (± 10.7)
Heart rate (beats/min) Day 122	-3.3 (± 10.8)	-1.2 (± 13.4)	-1.3 (± 7.6)	0.7 (± 16.0)
Heart rate (beats/min) Day 141	-1.3 (± 10.4)	0.8 (± 9.2)	2.0 (± 9.4)	2.2 (± 10.4)
Heart rate (beats/min) Day 169	0.7 (± 10.1)	0.5 (± 11.0)	3.0 (± 8.8)	1.5 (± 9.7)
Heart rate (beats/min) Day 197	2.1 (± 12.5)	2.3 (± 9.8)	1.7 (± 9.5)	1.8 (± 10.4)
Heart rate (beats/min) Day 225	0.9 (± 10.0)	1.2 (± 11.0)	2.5 (± 10.1)	1.8 (± 10.4)
Heart rate (beats/min) Day 253	-0.8 (± 12.2)	0.2 (± 11.0)	2.1 (± 10.0)	0.4 (± 9.4)
Heart rate (beats/min) Day 325/405	0.5 (± 10.4)	1.3 (± 9.8)	1.9 (± 9.4)	0.7 (± 9.9)
Weight (kg) Day 325/405	0.316 (± 4.550)	1.445 (± 4.863)	1.078 (± 4.714)	0.786 (± 5.348)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

During study follow-up (from day 1 to day 325/405). Day 325/405: for participants who completed the study under CSP Amendment 1 & 2, the end of study visits were Day 405 and Day 325, respectively.

Adverse event reporting additional description:

Subjects initially randomized to the 250 mg groups witched dose to 400 mg following CSP amendment 1 and were analysed according to the 400 mg group.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	MEDI6570 50 mg
Reporting group description: -	
Reporting group title	MEDI6570 400 mg
Reporting group description: -	
Reporting group title	PLACEBO
Reporting group description: -	
Reporting group title	MEDI6570 150 mg
Reporting group description: -	

Serious adverse events	MEDI6570 50 mg	MEDI6570 400 mg	PLACEBO
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 39 (10.26%)	10 / 126 (7.94%)	13 / 126 (10.32%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neuroendocrine tumour			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung adenocarcinoma			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			

subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
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			
Peripheral artery occlusion			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic aneurysm			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			

subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
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			
Acute myocardial infarction			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	3 / 126 (2.38%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 39 (0.00%)	2 / 126 (1.59%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (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
Coronary artery disease			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiogenic shock			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			

subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coronary artery stenosis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (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
Nervous system disorders			
Sciatica			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Retinal detachment			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Omental necrosis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
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	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (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
Incarcerated umbilical hernia			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (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

Ileal perforation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
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 polyp haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (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
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			

subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
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			
Stag horn calculus			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Urosepsis			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (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
Urinary tract infection bacterial			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			

subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (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
COVID-19			
subjects affected / exposed	1 / 39 (2.56%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	MEDI6570 150 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	17 / 129 (13.18%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Neuroendocrine tumour			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Lung adenocarcinoma			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Prostate cancer			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Peripheral artery occlusion			

subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aortic aneurysm			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral ischaemia			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Haemoptysis			
subjects affected / exposed	0 / 129 (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	2 / 129 (1.55%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Angina pectoris				
subjects affected / exposed	3 / 129 (2.33%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Angina unstable				
subjects affected / exposed	3 / 129 (2.33%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coronary artery disease				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiogenic shock				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac arrest				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac failure				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Coronary artery stenosis				

subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Sciatica			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transient ischaemic attack			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Retinal detachment			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Omental necrosis			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ileal perforation			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Gastrointestinal polyp haemorrhage			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain upper			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rectal haemorrhage			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cholecystitis acute			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			

Psoriasis			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Stag horn calculus			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Urosepsis			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection bacterial			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonitis			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
COVID-19			

subjects affected / exposed	0 / 129 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	MEDI6570 50 mg	MEDI6570 400 mg	PLACEBO
Total subjects affected by non-serious adverse events			
subjects affected / exposed	26 / 39 (66.67%)	79 / 126 (62.70%)	65 / 126 (51.59%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colorectal adenoma			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Haemangioma of liver			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Neoplasm skin			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 39 (5.13%)	9 / 126 (7.14%)	9 / 126 (7.14%)
occurrences (all)	2	9	9
Hypotension			
subjects affected / exposed	2 / 39 (5.13%)	4 / 126 (3.17%)	1 / 126 (0.79%)
occurrences (all)	2	5	1
Aortic aneurysm			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Aortic stenosis			

subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Haematoma			
subjects affected / exposed	1 / 39 (2.56%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	1	1	1
Hot flush			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Ischaemia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Peripheral artery stenosis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Peripheral coldness			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Phlebitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Raynaud's phenomenon			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Superior vena cava syndrome			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Non-cardiac chest pain			
subjects affected / exposed	2 / 39 (5.13%)	6 / 126 (4.76%)	4 / 126 (3.17%)
occurrences (all)	2	8	4
Pyrexia			

subjects affected / exposed	2 / 39 (5.13%)	3 / 126 (2.38%)	1 / 126 (0.79%)
occurrences (all)	2	4	1
Asthenia			
subjects affected / exposed	0 / 39 (0.00%)	4 / 126 (3.17%)	0 / 126 (0.00%)
occurrences (all)	0	5	0
Chest discomfort			
subjects affected / exposed	0 / 39 (0.00%)	3 / 126 (2.38%)	0 / 126 (0.00%)
occurrences (all)	0	3	0
Injection site urticaria			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Cyst			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	1 / 39 (2.56%)	5 / 126 (3.97%)	1 / 126 (0.79%)
occurrences (all)	1	5	1
Haemorrhagic cyst			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Hyperpyrexia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Induration			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Infusion site extravasation			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Injection site bruising			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
Injection site erythema			

subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Injection site haematoma			
subjects affected / exposed	0 / 39 (0.00%)	2 / 126 (1.59%)	0 / 126 (0.00%)
occurrences (all)	0	2	0
Injection site pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	2 / 126 (1.59%)
occurrences (all)	0	0	3
Injection site reaction			
subjects affected / exposed	1 / 39 (2.56%)	1 / 126 (0.79%)	2 / 126 (1.59%)
occurrences (all)	1	2	3
Injection site swelling			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Oedema peripheral			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	2 / 126 (1.59%)
occurrences (all)	0	0	3
Peripheral swelling			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Balanoposthitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Endometrial thickening			

subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Erectile dysfunction			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	2 / 126 (1.59%)
occurrences (all)	0	1	2
Genital tract inflammation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Gynaecomastia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Hydrometra			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Ovarian cyst			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 39 (2.56%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	1	1	1
Vaginal haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	2 / 39 (5.13%)	4 / 126 (3.17%)	3 / 126 (2.38%)
occurrences (all)	2	5	3
Epistaxis			
subjects affected / exposed	2 / 39 (5.13%)	2 / 126 (1.59%)	1 / 126 (0.79%)
occurrences (all)	2	4	1
Pleural effusion			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Atelectasis			

subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	2
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 39 (0.00%)	2 / 126 (1.59%)	0 / 126 (0.00%)
occurrences (all)	0	2	0
Nasal congestion			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Laryngospasm			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Hyperventilation			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Dyspnoea exertional			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	2 / 126 (1.59%)
occurrences (all)	0	0	2
Cough			
subjects affected / exposed	1 / 39 (2.56%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	1	1	1
Pleural thickening			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0

Pulmonary mass			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Pulmonary sarcoidosis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Sputum retention			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Throat irritation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Depressed mood			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 39 (0.00%)	2 / 126 (1.59%)	0 / 126 (0.00%)
occurrences (all)	0	2	0
Tension			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 39 (0.00%)	2 / 126 (1.59%)	0 / 126 (0.00%)
occurrences (all)	0	2	0
Nightmare			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Stress			

subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Drug abuse			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
Bacterial test positive			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Bleeding time prolonged			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
Heart rate increased			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Haemoglobin decreased			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram ST segment abnormal			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Ejection fraction decreased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Differential white blood cell count abnormal			

subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Blood pressure decreased			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Weight increased			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Weight decreased			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Vitamin D decreased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Transaminases increased			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Somatosensory evoked potentials abnormal			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
Injury, poisoning and procedural complications			
Road traffic accident			
subjects affected / exposed	1 / 39 (2.56%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	1	1	0
Arthropod sting			

subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Burns second degree			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 39 (0.00%)	4 / 126 (3.17%)	1 / 126 (0.79%)
occurrences (all)	0	7	1
Craniofacial fracture			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 39 (0.00%)	2 / 126 (1.59%)	0 / 126 (0.00%)
occurrences (all)	0	2	0
Foot fracture			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Immunisation reaction			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Joint injury			
subjects affected / exposed	0 / 39 (0.00%)	2 / 126 (1.59%)	0 / 126 (0.00%)
occurrences (all)	0	2	0
Ligament sprain			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Limb injury			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Muscle strain			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Post procedural haematoma			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Procedural pain			

subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Arthropod bite			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Scar			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Skin laceration			
subjects affected / exposed	0 / 39 (0.00%)	2 / 126 (1.59%)	0 / 126 (0.00%)
occurrences (all)	0	2	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	1 / 39 (2.56%)	3 / 126 (2.38%)	4 / 126 (3.17%)
occurrences (all)	1	4	4
Atrial fibrillation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	2 / 126 (1.59%)
occurrences (all)	0	0	3
Atrioventricular block first degree			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Ventricular extrasystoles			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Cardiac failure			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Coronary artery occlusion			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	1	0	1
Coronary artery stenosis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1

Extrasystoles			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Ischaemic cardiomyopathy			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Tachyarrhythmia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Sinus tachycardia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Sinus bradycardia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Palpitations			
subjects affected / exposed	0 / 39 (0.00%)	2 / 126 (1.59%)	2 / 126 (1.59%)
occurrences (all)	0	2	2
Myocardial infarction			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Mitral valve incompetence			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	2 / 126 (1.59%)
occurrences (all)	0	1	2
Bradycardia			
subjects affected / exposed	0 / 39 (0.00%)	2 / 126 (1.59%)	0 / 126 (0.00%)
occurrences (all)	0	2	0
Ventricular hypokinesia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Nervous system disorders			
Carotid arteriosclerosis			

subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Epilepsy			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	3	0
Carotid artery disease			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Carotid artery stenosis			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	1	0	1
Cerebral atrophy			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Cerebral small vessel ischaemic disease			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	1 / 39 (2.56%)	2 / 126 (1.59%)	3 / 126 (2.38%)
occurrences (all)	1	2	3
Dizziness postural			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Sciatica			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	1	0	1
Radiculopathy			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Presyncope			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	2	0

Peripheral sensory neuropathy			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 39 (0.00%)	2 / 126 (1.59%)	2 / 126 (1.59%)
occurrences (all)	0	2	2
Hand-eye coordination impaired			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Seizure			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Transient ischaemic attack			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Syncope			
subjects affected / exposed	0 / 39 (0.00%)	4 / 126 (3.17%)	0 / 126 (0.00%)
occurrences (all)	0	4	0
Spinal cord infarction			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Iron deficiency anaemia			

subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Increased tendency to bruise			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Granulomatous lymphadenitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	3 / 126 (2.38%)
occurrences (all)	0	1	3
Lymphadenopathy mediastinal			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis allergic			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Conjunctival suffusion			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Conjunctival haemorrhage			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Diabetic retinopathy			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Lacrimation increased			

subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Non-proliferative retinopathy			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Eye irritation			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	2 / 39 (5.13%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	2	1	1
Diarrhoea			
subjects affected / exposed	2 / 39 (5.13%)	2 / 126 (1.59%)	4 / 126 (3.17%)
occurrences (all)	2	2	4
Constipation			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Diverticulum intestinal			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Duodenitis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Abdominal discomfort			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
Abdominal distension			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0

Abdominal pain			
subjects affected / exposed	0 / 39 (0.00%)	2 / 126 (1.59%)	0 / 126 (0.00%)
occurrences (all)	0	2	0
Abdominal pain upper			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Anal fissure			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
Tooth erosion			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 39 (0.00%)	3 / 126 (2.38%)	0 / 126 (0.00%)
occurrences (all)	0	3	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	2 / 126 (1.59%)
occurrences (all)	0	0	2
Gingival bleeding			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
Haematochezia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1

Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Hiatus hernia			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	1	0	1
Large intestine polyp			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Mesenteric panniculitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
Small intestine ulcer			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Epigastric discomfort			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 39 (0.00%)	2 / 126 (1.59%)	0 / 126 (0.00%)
occurrences (all)	0	2	0
Hepatobiliary disorders			
Gallbladder cholesterolosis			

subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Hepatic steatosis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Decubitus ulcer			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Dermal cyst			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Ecchymosis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Intertrigo			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0

Pruritus			
subjects affected / exposed	1 / 39 (2.56%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	1	2	0
Psoriasis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 39 (2.56%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	1	1	1
Rash macular			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Skin hypertrophy			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Bladder hypertrophy			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Chronic kidney disease			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 39 (0.00%)	3 / 126 (2.38%)	0 / 126 (0.00%)
occurrences (all)	0	4	0
Renal colic			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
Renal cyst			

subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Graves' disease			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Hyperthyroidism			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Hypothyroidism			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	2 / 39 (5.13%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	2	1	2
Lumbar spinal stenosis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Arthralgia			
subjects affected / exposed	0 / 39 (0.00%)	2 / 126 (1.59%)	2 / 126 (1.59%)
occurrences (all)	0	2	2
Arthritis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	1 / 39 (2.56%)	3 / 126 (2.38%)	3 / 126 (2.38%)
occurrences (all)	1	4	3
Bursitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Costochondritis			

subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Joint swelling			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	0 / 39 (0.00%)	3 / 126 (2.38%)	0 / 126 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 39 (0.00%)	3 / 126 (2.38%)	3 / 126 (2.38%)
occurrences (all)	0	3	5
Osteoarthritis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Plantar fasciitis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Psoriatic arthropathy			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Rhabdomyolysis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Rotator cuff syndrome			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Spinal pain			

subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Tendon pain			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Influenza			
subjects affected / exposed	2 / 39 (5.13%)	2 / 126 (1.59%)	1 / 126 (0.79%)
occurrences (all)	2	2	1
Mastitis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Abscess oral			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Anal abscess			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
COVID-19			
subjects affected / exposed	2 / 39 (5.13%)	16 / 126 (12.70%)	6 / 126 (4.76%)
occurrences (all)	2	17	6
Conjunctivitis viral			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Diverticulitis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Fungal infection			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0

Gastroenteritis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
Gastroenteritis viral			
subjects affected / exposed	1 / 39 (2.56%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	1	1	0
Gingivitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 39 (2.56%)	3 / 126 (2.38%)	3 / 126 (2.38%)
occurrences (all)	1	3	3
Viral infection			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Osteomyelitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Otitis externa			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Periodontitis			
subjects affected / exposed	1 / 39 (2.56%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	1	1	1
Pneumonia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Pulpitis dental			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Purulence			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0

Respiratory tract infection			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
Sinusitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Tinea infection			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Tinea pedis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Tooth abscess			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
Tooth infection			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 39 (2.56%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	1	1	0
Urinary tract infection			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	1	0	1
Orchitis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
Decreased appetite			

subjects affected / exposed	1 / 39 (2.56%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	1	1	1
Dyslipidaemia			
subjects affected / exposed	0 / 39 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	1 / 39 (2.56%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	1	2	0
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 39 (2.56%)	0 / 126 (0.00%)	4 / 126 (3.17%)
occurrences (all)	1	0	4
Vitamin D deficiency			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Gout			
subjects affected / exposed	0 / 39 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	MEDI6570 150 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	87 / 129 (67.44%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colorectal adenoma			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Haemangioma of liver			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Neoplasm skin			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Hypertension			
subjects affected / exposed	4 / 129 (3.10%)		
occurrences (all)	5		
Hypotension			

subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Aortic aneurysm			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Aortic stenosis			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Haematoma			
subjects affected / exposed	2 / 129 (1.55%)		
occurrences (all)	2		
Hot flush			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Ischaemia			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Peripheral arterial occlusive disease			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Peripheral artery stenosis			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Peripheral coldness			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Phlebitis			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Raynaud's phenomenon			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Superior vena cava syndrome			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
General disorders and administration			

site conditions				
Non-cardiac chest pain				
subjects affected / exposed	5 / 129 (3.88%)			
occurrences (all)	5			
Pyrexia				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Asthenia				
subjects affected / exposed	2 / 129 (1.55%)			
occurrences (all)	2			
Chest discomfort				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Injection site urticaria				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Cyst				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Fatigue				
subjects affected / exposed	2 / 129 (1.55%)			
occurrences (all)	2			
Haemorrhagic cyst				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Hyperpyrexia				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Induration				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Influenza like illness				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Infusion site extravasation				

subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Injection site bruising			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Injection site erythema			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Injection site haematoma			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Injection site pain			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Injection site reaction			
subjects affected / exposed	2 / 129 (1.55%)		
occurrences (all)	3		
Injection site swelling			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	2		
Chest pain			
subjects affected / exposed	2 / 129 (1.55%)		
occurrences (all)	2		
Malaise			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Peripheral swelling			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Balanoposthitis			

subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Prostatitis			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Endometrial thickening			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Erectile dysfunction			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Genital tract inflammation			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Gynaecomastia			
subjects affected / exposed	2 / 129 (1.55%)		
occurrences (all)	2		
Hydrometra			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Ovarian cyst			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Vaginal haemorrhage			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	3 / 129 (2.33%)		
occurrences (all)	4		
Epistaxis			

subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Pleural effusion				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Atelectasis				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Oropharyngeal pain				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Nasal congestion				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Laryngospasm				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Hyperventilation				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Haemoptysis				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Dyspnoea exertional				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Cough				
subjects affected / exposed	5 / 129 (3.88%)			
occurrences (all)	5			
Pleural thickening				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			

Productive cough			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Pulmonary embolism			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Pulmonary mass			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Pulmonary sarcoidosis			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Sputum retention			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Throat irritation			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 129 (1.55%)		
occurrences (all)	2		
Depressed mood			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Depression			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Tension			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Insomnia			

subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Nightmare			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Stress			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Drug abuse			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Bacterial test positive			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Bleeding time prolonged			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 129 (1.55%)		
occurrences (all)	3		
Heart rate increased			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Haemoglobin decreased			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Electrocardiogram ST segment abnormal			

subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Ejection fraction decreased				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Differential white blood cell count abnormal				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Blood pressure increased				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Blood pressure decreased				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Hepatic enzyme increased				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Weight increased				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Weight decreased				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Vitamin D decreased				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Transaminases increased				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Somatosensory evoked potentials abnormal				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
SARS-CoV-2 test positive				

subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Road traffic accident			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Arthropod sting			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Burns second degree			
subjects affected / exposed	2 / 129 (1.55%)		
occurrences (all)	2		
Contusion			
subjects affected / exposed	2 / 129 (1.55%)		
occurrences (all)	2		
Craniofacial fracture			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Fall			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Foot fracture			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Immunisation reaction			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Joint injury			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Ligament sprain			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Limb injury			

subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Muscle strain			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Post procedural haematoma			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Procedural pain			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Arthropod bite			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Scar			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Skin laceration			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	7 / 129 (5.43%)		
occurrences (all)	7		
Atrial fibrillation			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Atrioventricular block first degree			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Ventricular extrasystoles			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Cardiac failure			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		

Cardiac ventricular thrombosis subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0			
Coronary artery occlusion subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0			
Coronary artery stenosis subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0			
Extrasystoles subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0			
Ischaemic cardiomyopathy subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0			
Tachycardia subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0			
Tachyarrhythmia subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0			
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0			
Sinus bradycardia subjects affected / exposed occurrences (all)	1 / 129 (0.78%) 1			
Palpitations subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0			
Myocardial infarction subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0			
Mitral valve incompetence subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0			

Bradycardia			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Ventricular hypokinesia			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Carotid arteriosclerosis			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Epilepsy			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Carotid artery disease			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Carotid artery stenosis			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Cerebral atrophy			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Cerebral small vessel ischaemic disease			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	6 / 129 (4.65%)		
occurrences (all)	6		
Dizziness postural			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Dysgeusia			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Sciatica			

subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Radiculopathy				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Presyncope				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Peripheral sensory neuropathy				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Paraesthesia				
subjects affected / exposed	2 / 129 (1.55%)			
occurrences (all)	2			
Hypoaesthesia				
subjects affected / exposed	2 / 129 (1.55%)			
occurrences (all)	2			
Headache				
subjects affected / exposed	2 / 129 (1.55%)			
occurrences (all)	2			
Hand-eye coordination impaired				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Seizure				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Transient ischaemic attack				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Syncope				
subjects affected / exposed	2 / 129 (1.55%)			
occurrences (all)	3			
Spinal cord infarction				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Somnolence				

subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Iron deficiency anaemia			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Increased tendency to bruise			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Granulomatous lymphadenitis			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Anaemia			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Lymphadenopathy mediastinal			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Ear and labyrinth disorders			
Tinnitus			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Eye disorders			
Conjunctivitis allergic			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Conjunctival suffusion			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Conjunctival haemorrhage			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Diabetic retinopathy			

subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	2		
Eye pain			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Lacrimation increased			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Non-proliferative retinopathy			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Ocular hyperaemia			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Eye irritation			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Diarrhoea			
subjects affected / exposed	5 / 129 (3.88%)		
occurrences (all)	5		
Constipation			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Diverticulum intestinal			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Duodenitis			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		

Abdominal discomfort				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Abdominal distension				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Abdominal pain				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Abdominal pain upper				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Anal fissure				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Colitis				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Dyspepsia				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Tooth erosion				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Flatulence				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Gastritis				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Gastrointestinal disorder				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Gastrooesophageal reflux disease				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			

Gingival bleeding				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Haematochezia				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Haemorrhoidal haemorrhage				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Haemorrhoids				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Hiatus hernia				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Large intestine polyp				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Mesenteric panniculitis				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Rectal haemorrhage				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Small intestine ulcer				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Stomatitis				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Epigastric discomfort				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Toothache				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			

Vomiting			
subjects affected / exposed	4 / 129 (3.10%)		
occurrences (all)	4		
Hepatobiliary disorders			
Gallbladder cholesterolosis			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Hepatic steatosis			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Decubitus ulcer			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Dermal cyst			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Dermatitis			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Dry skin			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Ecchymosis			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Eczema			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Erythema			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Hyperkeratosis			

subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Intertrigo			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Psoriasis			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	2 / 129 (1.55%)		
occurrences (all)	2		
Rash macular			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Skin hypertrophy			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Hyperhidrosis			
subjects affected / exposed	2 / 129 (1.55%)		
occurrences (all)	3		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Bladder hypertrophy			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Chronic kidney disease			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Haematuria			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		

Renal colic			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Renal cyst			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Renal impairment			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Endocrine disorders			
Graves' disease			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Hyperthyroidism			
subjects affected / exposed	2 / 129 (1.55%)		
occurrences (all)	2		
Hypothyroidism			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Pain in extremity			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Lumbar spinal stenosis			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Arthralgia			
subjects affected / exposed	2 / 129 (1.55%)		
occurrences (all)	2		
Arthritis			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	4 / 129 (3.10%)		
occurrences (all)	4		
Bursitis			

subjects affected / exposed	2 / 129 (1.55%)			
occurrences (all)	2			
Costochondritis				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Intervertebral disc protrusion				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Joint swelling				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Muscle spasms				
subjects affected / exposed	3 / 129 (2.33%)			
occurrences (all)	3			
Musculoskeletal discomfort				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Musculoskeletal pain				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Myalgia				
subjects affected / exposed	2 / 129 (1.55%)			
occurrences (all)	2			
Osteoarthritis				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Plantar fasciitis				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Psoriatic arthropathy				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Rhabdomyolysis				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Rotator cuff syndrome				

subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	2		
Spinal pain			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Tendon pain			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Muscular weakness			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Infections and infestations			
Influenza			
subjects affected / exposed	4 / 129 (3.10%)		
occurrences (all)	4		
Mastitis			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Abscess oral			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Anal abscess			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Bronchitis			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
COVID-19			
subjects affected / exposed	8 / 129 (6.20%)		
occurrences (all)	8		
Conjunctivitis viral			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Diverticulitis			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		

Fungal infection				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Gastroenteritis viral				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Gingivitis				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Lower respiratory tract infection				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	4 / 129 (3.10%)			
occurrences (all)	4			
Viral infection				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Osteomyelitis				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Otitis externa				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Periodontitis				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			
Pneumonia				
subjects affected / exposed	1 / 129 (0.78%)			
occurrences (all)	1			
Pulpitis dental				
subjects affected / exposed	0 / 129 (0.00%)			
occurrences (all)	0			

Purulence subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0		
Respiratory tract infection subjects affected / exposed occurrences (all)	1 / 129 (0.78%) 1		
Sinusitis subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0		
Tinea infection subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0		
Tinea pedis subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0		
Tooth abscess subjects affected / exposed occurrences (all)	1 / 129 (0.78%) 1		
Tooth infection subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	4 / 129 (3.10%) 4		
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0		
Orchitis subjects affected / exposed occurrences (all)	0 / 129 (0.00%) 0		
Viral upper respiratory tract infection subjects affected / exposed occurrences (all)	1 / 129 (0.78%) 1		
Metabolism and nutrition disorders Diabetes mellitus			

subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Decreased appetite			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Dyslipidaemia			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Hypokalaemia			
subjects affected / exposed	1 / 129 (0.78%)		
occurrences (all)	1		
Type 2 diabetes mellitus			
subjects affected / exposed	2 / 129 (1.55%)		
occurrences (all)	2		
Vitamin D deficiency			
subjects affected / exposed	0 / 129 (0.00%)		
occurrences (all)	0		
Gout			
subjects affected / exposed	2 / 129 (1.55%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 November 2021	The overall rationale for the amendment, given the complexity and burden of the current trial configuration and the corresponding impact on recruitment, is to simplify the protocol to reduce the patient burden and be more patient-centric. The protocol has a reduced total sample size while maintaining the assessment of the primary endpoint at a slightly reduced power and increased type 1 error.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported