Clinical trial results:
Obicetrapib on Top of Maximum Tolerated Lipid-Modifying Therapies (BROADWAY): A Placebo-Controlled, Double-Blind, Randomized Phase 3 Study to Evaluate the Effect of 10 mg Obicetrapib in Participants With Underlying HeFH and/or Atherosclerotic Cardiovascular Disease (ASCVD) Who are Not Adequately Controlled by Their Lipid Modifying Therapies

Summary

EudraCT number	2021-005065-40
Trial protocol	NL DK CZ
Global end of trial date	26 September 2024

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	TA-8995-302

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05142722
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	NewAmsterdam Pharma B.V.
Sponsor organisation address	Gooimeer 2-35, DC Naarden, Netherlands, 1411
Public contact	Study Director, NewAmsterdam Pharma B.V., +31 35 2062971 , study.director@newamsterdampharma.com
Scientific contact	Study Director, NewAmsterdam Pharma B.V., +31 35 2062971 , study.director@newamsterdampharma.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	27 February 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	26 September 2024
Global end of trial reached?	Yes
Global end of trial date	26 September 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to evaluate the effect of obicetrapib on LDL-C levels at Day 84.

Protection of trial subjects:

The study was conducted in accordance with the Declaration of Helsinki and with all applicable laws and regulations of the locale and country where the study was conducted, and in compliance with Good Clinical Practice Guidelines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 December 2021
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	Netherlands: 226
Country: Number of subjects enrolled	Poland: 403
Country: Number of subjects enrolled	Czechia: 161
Country: Number of subjects enrolled	Denmark: 91
Country: Number of subjects enrolled	United States: 904
Country: Number of subjects enrolled	China: 317
Country: Number of subjects enrolled	Japan: 130
Country: Number of subjects enrolled	Georgia: 298
Worldwide total number of subjects	2530
EEA total number of subjects	881

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)	1066
From 65 to 84 years	1437
85 years and over	27

Subject disposition

Recruitment

Recruitment details:

4214 patients were screened: out of 4214, 2530 participants were randomized (2:1) (obicetrapib: placebo): 1686 participants to the obicetrapib 10 mg group and 844 participants to the placebo group

Pre-assignment

Screening details:

4214 patients were screened

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, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

one placebo tablet once daily;
Placebo: placebo tablet made to resemble active

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

Dosage and administration details:

once daily matching placebo tablet

Arm title	Obicetrapib 10 mg

Arm description:

one 10 mg obicetrapib tablet once daily;
Obicetrapib: 10 mg obicetrapib tablet

Arm type	Experimental
Investigational medicinal product name	Obicetrapib 10 mg tablet
Investigational medicinal product code	TA-8995
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Dosage and administration details:
once daily 10 mg obicetrapib tablet

Number of subjects in period 1	Placebo	Obicetrapib 10 mg
Started	844	1686
Completed	795	1600
Not completed	49	86
Consent withdrawn by subject	20	27
Physician decision	-	1
Adverse event, non-fatal	2	1
Death	11	17
Participant Moved Away	-	2
Lost to follow-up	16	38

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
one placebo tablet once daily; Placebo: placebo tablet made to resemble active	
Reporting group title	Obicetrapib 10 mg
Reporting group description:	
one 10 mg obicetrapib tablet once daily; Obicetrapib: 10 mg obicetrapib tablet	

Reporting group values	Placebo	Obicetrapib 10 mg	Total
Number of subjects	844	1686	2530
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	360	706	1066
From 65-84 years	469	968	1437
85 years and over	15	12	27
Age continuous Units: years			
arithmetic mean	65.3	65.4	
standard deviation	± 9.61	± 9.90	-
Gender categorical Units: Subjects			
Female	280	573	853
Male	564	1113	1677
Ethnicity Units: Subjects			
Hispanic or Latino	46	80	126
Not Hispanic or Latino	798	1605	2403
Unknown or Not Reported	0	1	1
Race Units: Subjects			
American Indian or Alaska Native	1	5	6
Asian	150	312	462
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	39	112	151
White	647	1241	1888
More than one race	2	7	9
Unknown or Not Reported	5	9	14

Baseline Low-Density Lipoprotein Cholesterol (LDL-C)			
Baseline LDL-C is defined as the last measurement prior to the first dose of study drug. LDL-C was measured by Preparative Ultracentrifugation (PUC).			
Units: mg/dL			
arithmetic mean	98.4	98.1	
standard deviation	± 37.94	± 37.05	-

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
one placebo tablet once daily; Placebo: placebo tablet made to resemble active	
Reporting group title	Obicetrapib 10 mg
Reporting group description:	
one 10 mg obicetrapib tablet once daily; Obicetrapib: 10 mg obicetrapib tablet	

Primary: 1. Percent Change in Low-Density Lipoprotein Cholesterol (LDL-C) From Baseline to Day 84 [PUC]

End point title	1. Percent Change in Low-Density Lipoprotein Cholesterol (LDL-C) From Baseline to Day 84 [PUC]
End point description:	
LS mean percent change from baseline to Day 84 in Low-Density Lipoprotein Cholesterol (LDL-C) in the obicetrapib group compared to the placebo group [PUC]. LDL-C level was measured by preparative ultracentrifugation (PUC).	
End point type	Primary
End point timeframe:	
84 Days	

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	842	1679		
Units: Percent Change from Baseline				
least squares mean (standard error)	2.70 (± 1.571)	-29.94 (± 1.104)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Obicetrapib 10 mg v Placebo
Number of subjects included in analysis	2521
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares (LS) Mean
Point estimate	-32.65

Confidence interval	
level	95 %
sides	2-sided
lower limit	-35.79
upper limit	-29.5
Variability estimate	Standard error of the mean
Dispersion value	1.602

Secondary: 2. Percent Change in Low Density Lipoprotein-Cholesterol (LDL-C) From Baseline to Day 180 [Martin/Hopkins]

End point title	2. Percent Change in Low Density Lipoprotein-Cholesterol (LDL-C) From Baseline to Day 180 [Martin/Hopkins]

End point description:

LS mean percent change from baseline to Day 180 in Low-Density Lipoprotein Cholesterol (LDL-C) in the obicetrapib group compared to the placebo group [Martin/Hopkins]. LDL-C value was calculated using the Martin/Hopkins equation unless TG >= 400 mg/dL or LDL-C <= 50 mg/dL; where, LDL-C value was measured directly by preparative ultracentrifugation (PUC).

End point type	Secondary

End point timeframe:

180 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	4.68 (± 1.625)	-29.09 (± 1.176)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Obicetrapib 10 mg
Number of subjects included in analysis	2528
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares (LS) Mean
Point estimate	-33.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-37.07
upper limit	-30.49

Variability estimate	Standard error of the mean
Dispersion value	1.678

Secondary: 3. Percent Change in Low Density Lipoprotein-Cholesterol (LDL-C) From Baseline to Day 365 [PUC]

End point title	3. Percent Change in Low Density Lipoprotein-Cholesterol (LDL-C) From Baseline to Day 365 [PUC]

End point description:

LS mean percent change from baseline to Day 365 in Low-Density Lipoprotein Cholesterol (LDL-C) in the obicetrapib group compared to the placebo group [PUC]. LDL-C level was measured by preparative ultracentrifugation (PUC).

End point type	Secondary

End point timeframe:

365 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	842	1679		
Units: percent change from baseline				
least squares mean (standard error)	-1.27 (± 1.798)	-25.25 (± 1.480)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Obicetrapib 10 mg
Number of subjects included in analysis	2521
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [1]
Method	ANCOVA
Parameter estimate	Least Squares (LS) Mean
Point estimate	-23.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.87
upper limit	-20.09
Variability estimate	Standard error of the mean
Dispersion value	1.979

Notes:

[1] - The hierarchical testing procedure would only be conducted if the previous secondary efficacy endpoint reached a statistically significant treatment effect at p-value <0.05

Secondary: 4. Percent Change in Apolipoprotein B (ApoB) From Baseline to Day 84

End point title	4. Percent Change in Apolipoprotein B (ApoB) From Baseline to Day 84

End point description:

LS mean percent change from baseline to Day 84 in apolipoprotein B (ApoB) in obicetrapib group compared to the placebo group.

End point type	Secondary

End point timeframe:

84 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	1.08 (± 0.911)	-17.84 (± 0.669)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Obicetrapib 10 mg
Number of subjects included in analysis	2528
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [2]
Method	ANCOVA
Parameter estimate	Least Squares (LS) Mean
Point estimate	-18.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.76
upper limit	-17.09
Variability estimate	Standard error of the mean
Dispersion value	0.936

Notes:

[2] - The hierarchical testing procedure would only be conducted if the previous secondary efficacy endpoint reached a statistically significant treatment effect at p-value<0.05

Secondary: 5. Percent Change in Apolipoprotein B (ApoB) From Baseline to Day 180

End point title	5. Percent Change in Apolipoprotein B (ApoB) From Baseline to Day 180

End point description:

LS mean percent change from baseline to Day 180 in apolipoprotein B (ApoB) in obicetrapib group compared to the placebo group.

End point type	Secondary

End point timeframe:

180 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	2.23 (± 1.033)	-16.07 (± 0.742)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Obicetrapib 10 mg
Number of subjects included in analysis	2528
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [3]
Method	ANCOVA
Parameter estimate	Least Squares (LS) Mean
Point estimate	-18.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.38
upper limit	-16.23
Variability estimate	Standard error of the mean
Dispersion value	1.057

Notes:

[3] - The hierarchical testing procedure would only be conducted if the previous secondary efficacy endpoint reached a statistically significant treatment effect at p-value<0.05

Secondary: 6. Percent Change in Apolipoprotein B (ApoB) From Baseline to Day 365

End point title	6. Percent Change in Apolipoprotein B (ApoB) From Baseline to Day 365

End point description:

LS mean percent change from baseline to Day 365 in apolipoprotein B (ApoB) in obicetrapib group compared to the placebo group.

End point type	Secondary

End point timeframe:

365 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	-1.77 (± 1.165)	-15.57 (± 0.914)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Obicetrapib 10 mg
Number of subjects included in analysis	2528
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [4]
Method	ANCOVA
Parameter estimate	Least Squares (LS) Mean
Point estimate	-13.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.2
upper limit	-11.41
Variability estimate	Standard error of the mean
Dispersion value	1.219

Notes:

[4] - The hierarchical testing procedure would only be conducted if the previous secondary efficacy endpoint reached a statistically significant treatment effect at p-value<0.05

Secondary: 7. Percent Change in Non-HDL-C From Baseline to Day 84

End point title	7. Percent Change in Non-HDL-C From Baseline to Day 84

End point description:

LS mean percent change from baseline to Day 84 in Non-high-density Lipoprotein Cholesterol (Non-HDL-C) in obicetrapib group compared to the placebo group.

End point type	Secondary

End point timeframe:

84 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	2.81 (± 1.212)	-26.64 (± 0.892)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Obicetrapib 10 mg v Placebo
Number of subjects included in analysis	2528
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [5]
Method	ANCOVA
Parameter estimate	Least Squares (LS) Mean
Point estimate	-29.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.89
upper limit	-26.99
Variability estimate	Standard error of the mean
Dispersion value	1.251

Notes:

[5] - The hierarchical testing procedure would only be conducted if the previous secondary efficacy endpoint reached a statistically significant treatment effect at p-value<0.05

Secondary: 8. Percent Change in Non-HDL-C From Baseline to Day 180

End point title	8. Percent Change in Non-HDL-C From Baseline to Day 180

End point description:

LS mean percent change from baseline to Day 180 in Non-high-density Lipoprotein Cholesterol (non-HDL-C) in obicetrapib group compared to the placebo group.

End point type	Secondary

End point timeframe:

180 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	3.68 (± 1.302)	-24.63 (± 0.972)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Obicetrapib 10 mg
Number of subjects included in analysis	2528
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [6]
Method	ANCOVA
Parameter estimate	Least Squares (LS) Mean
Point estimate	-28.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.94
upper limit	-25.69
Variability estimate	Standard error of the mean
Dispersion value	1.339

Notes:

[6] - The hierarchical testing procedure would only be conducted if the previous secondary efficacy endpoint reached a statistically significant treatment effect at p-value<0.05

Secondary: 9. Percent Change in Non-HDL-C From Baseline to Day 365

End point title	9. Percent Change in Non-HDL-C From Baseline to Day 365

End point description:

LS mean percent change from baseline to Day 365 in Non-high-density Lipoprotein Cholesterol (non-HDL-C) in obicetrapib group compared to the placebo group.

End point type	Secondary

End point timeframe:

365 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	0.63 (± 1.480)	-22.38 (± 1.186)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Obicetrapib 10 mg

Number of subjects included in analysis	2528
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [7]
Method	ANCOVA
Parameter estimate	Least Squares (LS) Mean
Point estimate	-23.02
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.09
upper limit	-19.95
Variability estimate	Standard error of the mean
Dispersion value	1.564

Notes:

[7] - The hierarchical testing procedure would only be conducted if the previous secondary efficacy endpoint reached a statistically significant treatment effect at p-value<0.05

Secondary: 10. Percent Change in HDL-C From Baseline to Day 84

End point title	10. Percent Change in HDL-C From Baseline to Day 84

End point description:

LS mean percent change from baseline to Day 84 in High-density Lipoprotein Cholesterol (HDL-C) in obicetrapib group compared to the placebo group.

End point type	Secondary

End point timeframe:

84 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	0.61 (± 1.391)	136.87 (± 1.857)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Obicetrapib 10 mg
Number of subjects included in analysis	2528
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Least Squares (LS) Mean
Point estimate	136.26

Confidence interval	
level	95 %
sides	2-sided
lower limit	132.46
upper limit	140.07
Variability estimate	Standard error of the mean
Dispersion value	1.939

Secondary: 11. Percent Change in HDL-C From Baseline to Day 180

End point title	11. Percent Change in HDL-C From Baseline to Day 180
End point description:	
LS mean percent change from baseline to Day 180 in High-density Lipoprotein Cholesterol (HDL-C) in obicetrapib group compared to the placebo group.	
End point type	Secondary
End point timeframe:	
180 Days	

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	1.18 (± 1.897)	135.61 (± 2.192)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Obicetrapib 10 mg
Number of subjects included in analysis	2528
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [8]
Method	ANCOVA
Parameter estimate	Least Squares (LS) Mean
Point estimate	134.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	129.84
upper limit	139.03
Variability estimate	Standard error of the mean
Dispersion value	2.343

Notes:

[8] - The hierarchical testing procedure would only be conducted if the previous secondary efficacy endpoint reached a statistically significant treatment effect at p-value<0.05

Secondary: 12. Percent Change in HDL-C From Baseline to Day 365

End point title	12. Percent Change in HDL-C From Baseline to Day 365

End point description:

LS mean percent change from baseline to Day 365 in High-density Lipoprotein Cholesterol (HDL-C) in obicetrapib group compared to the placebo group.

End point type	Secondary

End point timeframe:

365 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	3.36 (± 1.651)	125.40 (± 2.193)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Obicetrapib 10 mg v Placebo
Number of subjects included in analysis	2528
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001 [9]
Method	ANCOVA
Parameter estimate	Least Squares (LS) Mean
Point estimate	122.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	117.53
upper limit	126.55
Variability estimate	Standard error of the mean
Dispersion value	2.299

Notes:

[9] - The hierarchical testing procedure would only be conducted if the previous secondary efficacy endpoint reached a statistically significant treatment effect at p-value<0.05

Secondary: 13. Percent Change in Lp(a) From Baseline to Day 84

End point title	13. Percent Change in Lp(a) From Baseline to Day 84

End point description:

LS mean percent change from baseline to Day 84 in Lipoprotein (a) [Lp(a)] in obicetrapib group compared to the placebo group.

End point type	Secondary

End point timeframe:

84 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	13.65 (± 8.240)	-0.48 (± 19.855)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Placebo v Obicetrapib 10 mg
Number of subjects included in analysis	2528
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4841 [10]
Method	ANCOVA
Parameter estimate	Least Squares (LS) Mean
Point estimate	-14.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-53.68
upper limit	25.44
Variability estimate	Standard error of the mean
Dispersion value	20.183

Notes:

[10] - The hierarchical testing procedure would only be conducted if the previous secondary efficacy endpoint reached a statistically significant treatment effect at p-value<0.05; therefore hierarchical testing was stopped for subsequent secondary endpoints

Secondary: 14. Percent Change in Apolipoprotein A1 (ApoA1) From Baseline to Day 84

End point title	14. Percent Change in Apolipoprotein A1 (ApoA1) From Baseline to Day 84

End point description:

LS mean percent change from baseline to Day 84 in Apolipoprotein A1 (ApoA1) in obicetrapib group compared to the placebo group.

End point type	Secondary

End point timeframe:

84 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	0.26 (± 0.597)	43.44 (± 0.686)		

Statistical analyses

No statistical analyses for this end point

Secondary: 15. Percent Change in Total Cholesterol From Baseline to Day 84

End point title	15. Percent Change in Total Cholesterol From Baseline to Day 84

End point description:

LS mean percent change from baseline to Day 84 in Total Cholesterol (TC) in obicetrapib group compared to the placebo group.

End point type	Secondary

End point timeframe:

84 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	-0.02 (± 0.757)	17.66 (± 0.702)		

Statistical analyses

No statistical analyses for this end point

Secondary: 16. Percent Change in Total Cholesterol From Baseline to Day 180

End point title	16. Percent Change in Total Cholesterol From Baseline to Day 180

End point description:

LS mean percent change from baseline to Day 180 in Total Cholesterol in obicetrapib group compared to the placebo group.

End point type	Secondary

End point timeframe:

180 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	0.85 (± 0.893)	18.68 (± 0.769)		

Statistical analyses

No statistical analyses for this end point

Secondary: 17. Percent Change in Total Cholesterol From Baseline to Day 365

End point title	17. Percent Change in Total Cholesterol From Baseline to Day 365

End point description:

LS mean percent change from baseline to Day 365 in Total Cholesterol in obicetrapib group compared to the placebo group.

End point type	Secondary

End point timeframe:

365 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	-0.58 (± 1.030)	17.96 (± 0.886)		

Statistical analyses

No statistical analyses for this end point

Secondary: 18. Percent Change in Triglycerides From Baseline to Day 84

End point title	18. Percent Change in Triglycerides From Baseline to Day 84

End point description:

LS mean percent change from baseline to Day 84 in Triglycerides in obicetrapib group compared to the placebo group.

End point type	Secondary

End point timeframe:

84 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	7.66 (± 1.814)	-0.17 (± 1.445)		

Statistical analyses

No statistical analyses for this end point

Secondary: 19. Percent Change in Triglycerides From Baseline to Day 180

End point title	19. Percent Change in Triglycerides From Baseline to Day 180

End point description:

LS mean percent change from baseline to Day 180 in Triglycerides in obicetrapib group compared to the placebo group.

End point type	Secondary

End point timeframe:

180 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	8.22 (± 2.061)	0.25 (± 1.584)		

Statistical analyses

No statistical analyses for this end point

Secondary: 20. Percent Change in Triglycerides From Baseline to Day 365

End point title	20. Percent Change in Triglycerides From Baseline to Day 365

End point description:

LS mean percent change from baseline to Day 365 in Triglycerides in obicetrapib group compared to the placebo group.

End point type	Secondary

End point timeframe:

365 days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
least squares mean (standard error)	6.33 (± 2.135)	0.60 (± 1.781)		

Statistical analyses

No statistical analyses for this end point

Post-hoc: 21. Percent Change in Lp(a) From Baseline to Day 84 (Hodges-Lehman)

End point title	21. Percent Change in Lp(a) From Baseline to Day 84 (Hodges-Lehman)

End point description:

Median percent change from baseline to Day 84 in Lipoprotein (a) [Lp(a)] in obicetrapib group compared to the placebo group.

End point type	Post-hoc

End point timeframe:

84 Days

End point values	Placebo	Obicetrapib 10 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	843	1685		
Units: percent change from baseline				
median (inter-quartile range (Q1-Q3))	-0.9 (-15.7 to 13.0)	-32.3 (-62.8 to -4.7)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From first dose of study drug up to Week 54	
Adverse event reporting additional description:	
Safety Population included all participants who received at least 1 dose of any study drug.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
one placebo tablet once daily; Placebo: placebo tablet made to resemble active	
Reporting group title	Obicetrapib 10 mg
Reporting group description:	
one 10 mg Obicetrapib tablet once daily; Obicetrapib: 10 mg Obicetrapib tablet	

Serious adverse events	Placebo	Obicetrapib 10 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	117 / 843 (13.88%)	211 / 1685 (12.52%)	
number of deaths (all causes)	12	19	
number of deaths resulting from adverse events	12	19	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colon cancer			
subjects affected / exposed	2 / 843 (0.24%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	2 / 843 (0.24%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma pancreas			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Bladder transitional cell carcinoma			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer metastatic			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung adenocarcinoma			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm malignant			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Malignant melanoma			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma stage IV			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Metastases to central nervous system			

subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to liver			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal carcinoma			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Oesophageal squamous cell carcinoma			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatic carcinoma			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Papillary cystadenoma lymphomatosum			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Plasma cell myeloma			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer recurrent			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer			

subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cancer			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal neoplasm			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transitional cell carcinoma			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 843 (0.24%)	3 / 1685 (0.18%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	2 / 843 (0.24%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic stenosis			
subjects affected / exposed	1 / 843 (0.12%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 843 (0.00%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral artery occlusion			

subjects affected / exposed	1 / 843 (0.12%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic aneurysm			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive emergency			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iliac artery stenosis			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intermittent claudication			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral vascular disorder			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral venous disease			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Shock			

subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Varicose vein			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	2 / 843 (0.24%)	3 / 1685 (0.18%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	3 / 843 (0.36%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	1 / 843 (0.12%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Sudden cardiac death			
subjects affected / exposed	0 / 843 (0.00%)	3 / 1685 (0.18%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 3	
Asthenia			
subjects affected / exposed	2 / 843 (0.24%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Exercise tolerance decreased			
subjects affected / exposed	0 / 843 (0.00%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac death			

subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Chest discomfort			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fat necrosis			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular stent stenosis			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			

Benign prostatic hyperplasia			
subjects affected / exposed	2 / 843 (0.24%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	2 / 843 (0.24%)	4 / 1685 (0.24%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 3	
Chronic obstructive pulmonary disease			
subjects affected / exposed	2 / 843 (0.24%)	3 / 1685 (0.18%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	2 / 843 (0.24%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 843 (0.00%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea exertional			
subjects affected / exposed	2 / 843 (0.24%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	1 / 843 (0.12%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	1 / 843 (0.12%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Bronchial haemorrhage			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary alveolar haemorrhage			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Sleep apnoea syndrome			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vocal cord thickening			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Alcoholism			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cardiovascular somatic symptom disorder			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Mental status changes			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device malfunction			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
International normalised ratio increased			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Troponin increased			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
White blood cell count increased			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 843 (0.00%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint injury			

subjects affected / exposed	0 / 843 (0.00%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	0 / 843 (0.00%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropod bite			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Concussion			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniofacial injury			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delayed recovery from anaesthesia			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femur fracture			

subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb traumatic amputation			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Patella fracture			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax traumatic			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Road traffic accident			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			

subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sternal fracture			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haemorrhage			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thermal burn			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tibia fracture			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular graft thrombosis			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	10 / 843 (1.19%)	17 / 1685 (1.01%)	
occurrences causally related to treatment / all	0 / 10	0 / 18	
deaths causally related to treatment / all	0 / 2	0 / 1	
Angina unstable			

subjects affected / exposed	8 / 843 (0.95%)	17 / 1685 (1.01%)	
occurrences causally related to treatment / all	0 / 9	0 / 17	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	4 / 843 (0.47%)	7 / 1685 (0.42%)	
occurrences causally related to treatment / all	0 / 5	0 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	7 / 843 (0.83%)	3 / 1685 (0.18%)	
occurrences causally related to treatment / all	0 / 8	0 / 3	
deaths causally related to treatment / all	0 / 2	0 / 1	
Cardiac failure			
subjects affected / exposed	4 / 843 (0.47%)	5 / 1685 (0.30%)	
occurrences causally related to treatment / all	0 / 4	1 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	0 / 843 (0.00%)	7 / 1685 (0.42%)	
occurrences causally related to treatment / all	0 / 0	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute left ventricular failure			
subjects affected / exposed	4 / 843 (0.47%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	0 / 843 (0.00%)	6 / 1685 (0.36%)	
occurrences causally related to treatment / all	0 / 0	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 1	
Arteriosclerosis coronary artery			
subjects affected / exposed	1 / 843 (0.12%)	4 / 1685 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			

subjects affected / exposed	1 / 843 (0.12%)	4 / 1685 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	1 / 843 (0.12%)	3 / 1685 (0.18%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia			
subjects affected / exposed	2 / 843 (0.24%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 0	
Acute coronary syndrome			
subjects affected / exposed	2 / 843 (0.24%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	3 / 843 (0.36%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	2 / 843 (0.24%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 4	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac failure chronic			
subjects affected / exposed	0 / 843 (0.00%)	3 / 1685 (0.18%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic coronary syndrome			
subjects affected / exposed	2 / 843 (0.24%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery stenosis			

subjects affected / exposed	0 / 843 (0.00%)	3 / 1685 (0.18%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure acute			
subjects affected / exposed	0 / 843 (0.00%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular extrasystoles			
subjects affected / exposed	2 / 843 (0.24%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular fibrillation			
subjects affected / exposed	0 / 843 (0.00%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block second degree			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiogenic shock			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiovascular disorder			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular failure			

subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Microvascular coronary artery disease			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus node dysfunction			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular tachycardia			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebral infarction			
subjects affected / exposed	2 / 843 (0.24%)	7 / 1685 (0.42%)	
occurrences causally related to treatment / all	0 / 2	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	3 / 843 (0.36%)	6 / 1685 (0.36%)	
occurrences causally related to treatment / all	0 / 4	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	1 / 843 (0.12%)	7 / 1685 (0.42%)	
occurrences causally related to treatment / all	0 / 1	0 / 7	
deaths causally related to treatment / all	0 / 0	0 / 2	
Ischaemic stroke			

subjects affected / exposed	1 / 843 (0.12%)	4 / 1685 (0.24%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 1	0 / 0	
Syncope			
subjects affected / exposed	2 / 843 (0.24%)	3 / 1685 (0.18%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery stenosis			
subjects affected / exposed	1 / 843 (0.12%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic neuropathy			
subjects affected / exposed	0 / 843 (0.00%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic cerebral infarction			
subjects affected / exposed	1 / 843 (0.12%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ataxia			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain stem haemorrhage			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Dizziness			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysarthria			

subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Facial nerve disorder			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lacunar infarction			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Migraine with aura			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normal pressure hydrocephalus			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tension headache			

subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic encephalopathy			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vertebrobasilar insufficiency			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 843 (0.12%)	3 / 1685 (0.18%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iron deficiency anaemia			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Normocytic anaemia			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cataract nuclear			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 843 (0.00%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	1 / 843 (0.12%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal polyp			
subjects affected / exposed	1 / 843 (0.12%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal adhesions			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			

subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faecaloma			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus paralytic			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mesenteric artery thrombosis			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			

subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peptic ulcer haemorrhage			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal fissure			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	1 / 843 (0.12%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute hepatic failure			

subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary obstruction			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis chronic			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholelithiasis			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Skin ulcer			
subjects affected / exposed	0 / 843 (0.00%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperhidrosis			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	2 / 843 (0.24%)	5 / 1685 (0.30%)	
occurrences causally related to treatment / all	0 / 2	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	1 / 843 (0.12%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic kidney disease			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ureterolithiasis			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Primary hyperaldosteronism			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	2 / 843 (0.24%)	4 / 1685 (0.24%)	
occurrences causally related to treatment / all	0 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

Arthralgia			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest wall haematoma			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty arthritis			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc disorder			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Joint range of motion decreased			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb discomfort			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar spinal stenosis			

subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myopathy			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Temporomandibular joint syndrome			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	6 / 843 (0.71%)	9 / 1685 (0.53%)	
occurrences causally related to treatment / all	0 / 6	0 / 9	
deaths causally related to treatment / all	0 / 1	0 / 0	
Urinary tract infection			
subjects affected / exposed	3 / 843 (0.36%)	4 / 1685 (0.24%)	
occurrences causally related to treatment / all	0 / 3	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			

subjects affected / exposed	0 / 843 (0.00%)	4 / 1685 (0.24%)	
occurrences causally related to treatment / all	0 / 0	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	1 / 843 (0.12%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 843 (0.00%)	3 / 1685 (0.18%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	0 / 843 (0.00%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	1 / 843 (0.12%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis acute			
subjects affected / exposed	1 / 843 (0.12%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	1 / 843 (0.12%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 843 (0.00%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			

subjects affected / exposed	1 / 843 (0.12%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess oral			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchiolitis			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic sinusitis			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella infection			

subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenic sepsis			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parainfluenzae virus infection			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia influenzal			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural cellulitis			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhinitis			

subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superinfection bacterial			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 843 (0.12%)	3 / 1685 (0.18%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Diabetes mellitus inadequate control			
subjects affected / exposed	1 / 843 (0.12%)	2 / 1685 (0.12%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	1 / 843 (0.12%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic complication			

subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	1 / 843 (0.12%)	0 / 1685 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lactic acidosis			
subjects affected / exposed	0 / 843 (0.00%)	1 / 1685 (0.06%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo	Obicetrapib 10 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	241 / 843 (28.59%)	459 / 1685 (27.24%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	33 / 843 (3.91%)	82 / 1685 (4.87%)	
occurrences (all)	33	89	
Nervous system disorders			
Dizziness			
subjects affected / exposed	15 / 843 (1.78%)	40 / 1685 (2.37%)	
occurrences (all)	15	44	
Headache			
subjects affected / exposed	17 / 843 (2.02%)	43 / 1685 (2.55%)	
occurrences (all)	18	45	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	24 / 843 (2.85%)	38 / 1685 (2.26%)	
occurrences (all)	28	40	
Infections and infestations			
COVID-19			

subjects affected / exposed	48 / 843 (5.69%)	81 / 1685 (4.81%)	
occurrences (all)	49	81	
Nasopharyngitis			
subjects affected / exposed	22 / 843 (2.61%)	43 / 1685 (2.55%)	
occurrences (all)	26	55	
Upper respiratory tract infection			
subjects affected / exposed	33 / 843 (3.91%)	49 / 1685 (2.91%)	
occurrences (all)	35	54	
Urinary tract infection			
subjects affected / exposed	21 / 843 (2.49%)	39 / 1685 (2.31%)	
occurrences (all)	25	41	
Metabolism and nutrition disorders			
Hyperglycaemia			
subjects affected / exposed	28 / 843 (3.32%)	44 / 1685 (2.61%)	
occurrences (all)	33	46	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 December 2021	This amendment was developed to reflect an increase in the planned number of participants and sites, to modify the participant population, to provide additional guidance for serious adverse event (SAE) reporting, and to improve clarity and consistency within the study protocol.
11 January 2022	This amendment was developed to modify the participant population, to alter language regarding breaking the blind, and to improve clarity and consistency within the study protocol.
15 July 2022	This amendment was developed primarily to incorporate feedback from the United States Food and Drug Administration and to improve clarity and consistency within the study protocol
19 August 2022	This amendment was developed primarily to incorporate feedback from the United States Food and Drug Administration, to modify eligibility criteria in an effort to improve study enrollment, and to improve clarity and consistency within the study protocol.
30 December 2022	This amendment was developed to improve clarity and consistency within the study protocol.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported

Online references

http://www.ncbi.nlm.nih.gov/pubmed/38705341

http://www.ncbi.nlm.nih.gov/pubmed/40337982