Clinical trial results:
A Phase 1, 4-Period, Crossover, Open-label Study in Healthy Volunteers to Assess the Effect of Different Types of Food on a Single-dose of JNJ-64417184 Administered as Tablets.

Summary

EudraCT number	2019-003469-17
Trial protocol	
Global end of trial date	23 December 2019

Results information

Result version number	v1 (current)
This version publication date	01 January 2021
First version publication date	01 January 2021

Trial information

Trial identification

Sponsor protocol code	64417184RSV1006

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04121052
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Research & Development, LLC
Sponsor organisation address	Turnhoutseweg 30, B-2340, Beerse, Belgium, United States,
Public contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.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	23 December 2019

Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	23 December 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main purpose of this study was to evaluate the effect of 5 different food conditions on the single dose pharmacokinetic (PK) of the JNJ-64417184 tablet formulation administered orally, using the PK after a high-fat meal as a reference, in healthy adult subjects.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements. The safety evaluations included adverse events, clinical laboratory tests, electrocardiograms, Vital signs and physical examinations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 October 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 20
Worldwide total number of subjects	20
EEA total number of subjects	20

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)	20
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 20 subjects were randomized in the study; 19 subjects completed the study and 1 subject withdrawn the consent of study participation.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Arm title	JNJ-64417184 300 mg

Arm description:

Participants received JNJ-64417184 300 milligram (mg) tablet administered orally as a single dose under fed or fasted conditions. In 4 subsequent treatment periods, subjects received the treatments in a 16-sequence, 4-period
crossover design on Day 1 of each treatment period. The sequences were such that each subject received the reference treatment (high-fat meal) and 3 out of 4 other food conditions (standard meal, low-fat meal, Ensure Original, or fasted). Each drug intake was followed by a washout period of at least 7 days.

Arm type	Experimental
Investigational medicinal product name	JNJ-64417184
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet, Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

JNJ-64417184 300 mg was administered in fed condition under 4 food conditions (High-fat meal, standard meal, low-fat meal, Ensure Original).

Number of subjects in period 1	JNJ-64417184 300 mg
Started	20
Completed	19
Not completed	1
Consent withdrawn by subject	1

Baseline characteristics

Reporting groups

Reporting group title	JNJ-64417184 300 mg

Reporting group description:

Participants received JNJ-64417184 300 milligram (mg) tablet administered orally as a single dose under fed or fasted conditions. In 4 subsequent treatment periods, subjects received the treatments in a 16-sequence, 4-period
crossover design on Day 1 of each treatment period. The sequences were such that each subject received the reference treatment (high-fat meal) and 3 out of 4 other food conditions (standard meal, low-fat meal, Ensure Original, or fasted). Each drug intake was followed by a washout period of at least 7 days.

Reporting group values	JNJ-64417184 300 mg	Total	
Number of subjects	20	20	
Title for AgeCategorical Units: subjects			
Newborns (0-1 years)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	20	20	
From 65 to 84 years	0	0	
85 years and over	0	0	
Title for AgeContinuous Units: years			
median	32		
full range (min-max)	20 to 49	-	
Title for Gender Units: subjects			
Female	4	4	
Male	16	16	
Race Units: Subjects			
American Indian or Alaska Native	2	2	
Black or African American	1	1	
White	16	16	
Multiple	1	1	
Ethinicity Units: Subjects			
Hispanic or Latino	3	3	
Not Hispanic or Latino	17	17	

Subject analysis sets

Subject analysis set title	High-Fat Meal: JNJ-64417184 300 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subject received JNJ-64417184 300 mg after High-fat Meal as per assigned treatment sequences.

Subject analysis set title	Standard Meal: JNJ-64417184 300 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received JNJ-64417184 300 mg after Standard meal as per assigned treatment sequences.

Subject analysis set title	Low-Fat Meal: JNJ-64417184 300 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received JNJ-64417184 300 mg after Low-fat meal as per assigned treatment sequences.

Subject analysis set title	Ensure Original: JNJ-64417184 300 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received JNJ-64417184 300 mg after Ensure Original as per assigned treatment sequences.

Subject analysis set title	Fasted: JNJ-64417184 300 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subject received JNJ-64417184 300 mg under fasted condition as per assigned treatment sequences.

Reporting group values	High-Fat Meal: JNJ-64417184 300 mg	Standard Meal: JNJ-64417184 300 mg	Low-Fat Meal: JNJ-64417184 300 mg
Number of subjects	20	16	14
Title for AgeCategorical Units: subjects			
Newborns (0-1 years) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65 to 84 years 85 years and over	20	16	14
Title for AgeContinuous Units: years median full range (min-max)			
Title for Gender Units: subjects			
Female Male			
Race Units: Subjects			
American Indian or Alaska Native Black or African American White Multiple			
Ethinicity Units: Subjects			
Hispanic or Latino Not Hispanic or Latino			

Reporting group values	Ensure Original: JNJ-64417184 300 mg	Fasted: JNJ-64417184 300 mg	
Number of subjects	15	15	
Title for AgeCategorical Units: subjects			
Newborns (0-1 years) Children (2-11 years)			

Adolescents (12-17 years) Adults (18-64 years) From 65 to 84 years 85 years and over	15	15	
Title for AgeContinuous Units: years median full range (min-max)			
Title for Gender Units: subjects			
Female Male			
Race Units: Subjects			
American Indian or Alaska Native Black or African American White Multiple			
Ethinicity Units: Subjects			
Hispanic or Latino Not Hispanic or Latino			

End points

End points reporting groups

Reporting group title	JNJ-64417184 300 mg
Reporting group description:	
Participants received JNJ-64417184 300 milligram (mg) tablet administered orally as a single dose under fed or fasted conditions. In 4 subsequent treatment periods, subjects received the treatments in a 16-sequence, 4-period crossover design on Day 1 of each treatment period. The sequences were such that each subject received the reference treatment (high-fat meal) and 3 out of 4 other food conditions (standard meal, low-fat meal, Ensure Original, or fasted). Each drug intake was followed by a washout period of at least 7 days.	
Subject analysis set title	High-Fat Meal: JNJ-64417184 300 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subject received JNJ-64417184 300 mg after High-fat Meal as per assigned treatment sequences.	
Subject analysis set title	Standard Meal: JNJ-64417184 300 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received JNJ-64417184 300 mg after Standard meal as per assigned treatment sequences.	
Subject analysis set title	Low-Fat Meal: JNJ-64417184 300 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received JNJ-64417184 300 mg after Low-fat meal as per assigned treatment sequences.	
Subject analysis set title	Ensure Original: JNJ-64417184 300 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received JNJ-64417184 300 mg after Ensure Original as per assigned treatment sequences.	
Subject analysis set title	Fasted: JNJ-64417184 300 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subject received JNJ-64417184 300 mg under fasted condition as per assigned treatment sequences.	

Primary: Maximum Observed Plasma Concentration (Cmax) of JNJ-64417184 300 mg

End point title	Maximum Observed Plasma Concentration (Cmax) of JNJ-64417184 300 mg
End point description:	
Cmax is the maximum observed plasma concentration of JNJ-64417184 300 mg. Pharmacokinetic Analysis Set included all subjects who had received at least 1 dose of study drug and had at least 1 plasma concentration data value or 1 PK parameter value after study drug intake.	
End point type	Primary
End point timeframe:	
Predose, 0.5, 1, 2, 3, 4, 6, 8, 10, 12, 18, 24, 36, 48, 72, 96, 120 hours postdose	

End point values	High-Fat Meal: JNJ-64417184 300 mg	Standard Meal: JNJ-64417184 300 mg	Low-Fat Meal: JNJ-64417184 300 mg	Ensure Original: JNJ-64417184 300 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	16	14	15
Units: nanogram per milliliter (ng/mL)				
arithmetic mean (standard deviation)	11954 (± 3426)	11766 (± 4286)	6436 (± 3599)	9260 (± 3821)

End point values	Fasted: JNJ-64417184 300 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: nanogram per milliliter (ng/mL)				
arithmetic mean (standard deviation)	6359 (± 3239)			

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Subjects analyzed for both the arms as per assigned treatment sequence in respective periods were 20.	
Comparison groups	High-Fat Meal: JNJ-64417184 300 mg v Standard Meal: JNJ-64417184 300 mg
Number of subjects included in analysis	36
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio (percentage)
Point estimate	95.77
Confidence interval	
level	90 %
sides	2-sided
lower limit	79.28
upper limit	115.7
Variability estimate	Standard error of the mean
Dispersion value	33.9

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Subjects analyzed for both the arms as per assigned treatment sequence in respective periods were 20.	
Comparison groups	High-Fat Meal: JNJ-64417184 300 mg v Low-Fat Meal: JNJ-64417184 300 mg
Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	other

Parameter estimate	Geometric mean ratio (percentage)
Point estimate	48.65
Confidence interval	
level	90 %
sides	2-sided
lower limit	39.94
upper limit	59.27
Variability estimate	Standard error of the mean
Dispersion value	33.9

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
Subjects analyzed for both the arms as per assigned treatment sequence in respective periods were 20.	
Comparison groups	High-Fat Meal: JNJ-64417184 300 mg v Ensure Original: JNJ-64417184 300 mg
Number of subjects included in analysis	35
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio (percentage)
Point estimate	77.7
Confidence interval	
level	90 %
sides	2-sided
lower limit	64.08
upper limit	94.21
Variability estimate	Standard error of the mean
Dispersion value	33.9

Statistical analysis title	Statistical Analysis 4
Statistical analysis description:	
Subjects analyzed for both the arms as per assigned treatment sequence in respective periods were 20.	
Comparison groups	High-Fat Meal: JNJ-64417184 300 mg v Fasted: JNJ-64417184 300 mg
Number of subjects included in analysis	35
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio (percentage)
Point estimate	44.23
Confidence interval	
level	90 %
sides	2-sided
lower limit	36.46
upper limit	53.67
Variability estimate	Standard error of the mean
Dispersion value	33.9

Primary: Area Under The Plasma Concentration- Time Curve From Time 0 to Time of The Last Quantifiable (AUC [0-Last]) of JNJ-64417184 300 mg

End point title	Area Under The Plasma Concentration- Time Curve From Time 0 to Time of The Last Quantifiable (AUC [0-Last]) of JNJ-64417184 300 mg

End point description:

Area under the plasma analyte concentration- time curve from time 0 to time (AUC [0-Last]) of the last quantifiable (non-below quantification limit [non-BQL]) concentration, calculated by linear-linear trapezoidal summation of JNJ-64417184 300 mg. Pharmacokinetic Analysis Set included all subjects who had received at least 1 dose of study drug and had at least 1 plasma concentration data value or 1 PK parameter value after study drug intake. Here 'N' (Number of subjects analyzed) included all subjects evaluated for this endpoint.

End point type	Primary

End point timeframe:

Predose, 0.5, 1, 2, 3, 4, 6, 8, 10, 12, 18, 24, 36, 48, 72, 96, 120 hours postdose

End point values	High-Fat Meal: JNJ-64417184 300 mg	Standard Meal: JNJ-64417184 300 mg	Low-Fat Meal: JNJ-64417184 300 mg	Ensure Original: JNJ-64417184 300 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	15	14	15
Units: nanograms hour per milliliter (ng*h/mL)				
arithmetic mean (standard deviation)	302797 (± 89019)	304788 (± 107404)	158901 (± 78621)	228935 (± 100491)

End point values	Fasted: JNJ-64417184 300 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: nanograms hour per milliliter (ng*h/mL)				
arithmetic mean (standard deviation)	179858 (± 80030)			

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Subjects analyzed for both the arms as per assigned treatment sequence in respective periods were 20.

Comparison groups	High-Fat Meal: JNJ-64417184 300 mg v Standard Meal: JNJ-64417184 300 mg
Number of subjects included in analysis	35
Analysis specification	Pre-specified

Analysis type	other
Parameter estimate	Geometric mean ratio (percentage)
Point estimate	97.2
Confidence interval	
level	90 %
sides	2-sided
lower limit	82.5
upper limit	114.52
Variability estimate	Standard error of the mean
Dispersion value	28.3

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Subjects analyzed for both the arms as per assigned treatment sequence in respective periods were 20.	
Comparison groups	High-Fat Meal: JNJ-64417184 300 mg v Low-Fat Meal: JNJ-64417184 300 mg
Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio (percentage)
Point estimate	49.67
Confidence interval	
level	90 %
sides	2-sided
lower limit	42.06
upper limit	58.66
Variability estimate	Standard error of the mean
Dispersion value	28.3

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
Subjects analyzed for both the arms as per assigned treatment sequence in respective periods were 20.	
Comparison groups	High-Fat Meal: JNJ-64417184 300 mg v Ensure Original: JNJ-64417184 300 mg
Number of subjects included in analysis	35
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio (percentage)
Point estimate	77.5
Confidence interval	
level	90 %
sides	2-sided
lower limit	65.9
upper limit	91.15
Variability estimate	Standard error of the mean
Dispersion value	28.3

Statistical analysis title	Statistical Analysis 4
Statistical analysis description:	
Subjects analyzed for both the arms as per assigned treatment sequence in respective periods were 20.	
Comparison groups	High-Fat Meal: JNJ-64417184 300 mg v Fasted: JNJ-64417184 300 mg
Number of subjects included in analysis	35
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio (percentage)
Point estimate	48.33
Confidence interval	
level	90 %
sides	2-sided
lower limit	41.07
upper limit	56.86
Variability estimate	Standard error of the mean
Dispersion value	28.3

Primary: Area Under The Plasma Concentration-Time Curve (AUC) From Time 0 to Infinite Time (AUC[0-Infinity])

End point title	Area Under The Plasma Concentration-Time Curve (AUC) From Time 0 to Infinite Time (AUC[0-Infinity])

End point description:

Area under the plasma concentration-time curve (AUC) from time 0 to infinite time of JNJ-64417184 300 mg, calculated as AUClast + Clast/λz, where Clast is the last observed measurable (non-BQL) plasma concentration; extrapolations of more than 20% of the total AUC are reported as approximations. Pharmacokinetic Analysis Set included all subjects who had received at least 1 dose of study drug and had at least 1 plasma concentration data value or 1 PK parameter value after study drug intake. Here 'N' (Number of subjects analyzed) included all subjects evaluated for this endpoint.

End point type	Primary

End point timeframe:

Predose, 0.5, 1, 2, 3, 4, 6, 8, 10, 12, 18, 24, 36, 48, 72, 96, 120 hours postdose

End point values	High-Fat Meal: JNJ-64417184 300 mg	Standard Meal: JNJ-64417184 300 mg	Low-Fat Meal: JNJ-64417184 300 mg	Ensure Original: JNJ-64417184 300 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	15	14	15
Units: nanograms hour per milliliter (ng*h/mL)				
arithmetic mean (standard deviation)	307688 (± 90267)	310140 (± 107544)	163621 (± 79429)	233649 (± 100728)

End point values	Fasted: JNJ-64417184 300 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: nanograms hour per milliliter (ng*h/mL)				
arithmetic mean (standard deviation)	186300 (± 81715)			

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Subjects analyzed for both the arms as per assigned treatment sequence in respective periods were 20.	
Comparison groups	High-Fat Meal: JNJ-64417184 300 mg v Standard Meal: JNJ-64417184 300 mg
Number of subjects included in analysis	35
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio (percentage)
Point estimate	97.52
Confidence interval	
level	90 %
sides	2-sided
lower limit	83.18
upper limit	114.34
Variability estimate	Standard error of the mean
Dispersion value	27.4

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Subjects analyzed for both the arms as per assigned treatment sequence in respective periods were 20.	
Comparison groups	High-Fat Meal: JNJ-64417184 300 mg v Low-Fat Meal: JNJ-64417184 300 mg
Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio (percentage)
Point estimate	50.78
Confidence interval	
level	90 %
sides	2-sided
lower limit	43.21
upper limit	59.67
Variability estimate	Standard error of the mean
Dispersion value	27.4

Statistical analysis title	Statistical Analysis 3
Statistical analysis description: Subjects analyzed for both the arms as per assigned treatment sequence in respective periods were 20.	
Comparison groups	High-Fat Meal: JNJ-64417184 300 mg v Ensure Original: JNJ-64417184 300 mg
Number of subjects included in analysis	35
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio (percentage)
Point estimate	78.05
Confidence interval	
level	90 %
sides	2-sided
lower limit	66.68
upper limit	91.36
Variability estimate	Standard error of the mean
Dispersion value	27.4

Statistical analysis title	Statistical Analysis 4
Statistical analysis description: Subjects analyzed for both the arms as per assigned treatment sequence in respective periods were 20.	
Comparison groups	High-Fat Meal: JNJ-64417184 300 mg v Fasted: JNJ-64417184 300 mg
Number of subjects included in analysis	35
Analysis specification	Pre-specified
Analysis type	other
Parameter estimate	Geometric mean ratio (percentage)
Point estimate	49.61
Confidence interval	
level	90 %
sides	2-sided
lower limit	42.37
upper limit	58.09
Variability estimate	Standard error of the mean
Dispersion value	27.4

Secondary: Number of Subjects With Adverse Events (AEs) as a Measure of Safety and Tolerability

End point title	Number of Subjects With Adverse Events (AEs) as a Measure of Safety and Tolerability

End point description:

An AE is any untoward medical event that occurs in a participant administered an investigational product, and it does not necessarily indicate only events with clear causal relationship with the relevant investigational product. Safety analysis set included all randomized subjects who received at least 1 dose of study intervention and provided postbaseline safety data.

End point type	Secondary

End point timeframe:

Up to 28 days.

End point values	High-Fat Meal: JNJ-64417184 300 mg	Standard Meal: JNJ-64417184 300 mg	Low-Fat Meal: JNJ-64417184 300 mg	Ensure Original: JNJ-64417184 300 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	20	16	14	15
Units: Number of Subjects	7	9	6	7

End point values	Fasted: JNJ-64417184 300 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	15			
Units: Number of Subjects	7			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Up to 28 days	
Adverse event reporting additional description:	
Safety analysis set included all randomized subjects who received at least 1 dose of study intervention and provided post baseline safety data.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups	
Reporting group title	JNJ-64417184 300 mg
Reporting group description:	
JNJ-64417184 300 mg was administered in fed condition under 4 food conditions (High-fat meal, standard meal, low-fat meal, Ensure Original).	

Serious adverse events	JNJ-64417184 300 mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	JNJ-64417184 300 mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	16 / 20 (80.00%)		
Injury, poisoning and procedural complications			
Arthropod Bite			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Vascular Access Site Haematoma			
subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	3		
Wound			
subjects affected / exposed	1 / 20 (5.00%)		

occurrences (all)	1		

Respiratory, thoracic and mediastinal disorders			
Oropharyngeal Pain			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Nervous system disorders			
Dizziness			
subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	3		
Headache			
subjects affected / exposed	6 / 20 (30.00%)		
occurrences (all)	8		
Presyncope			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	2		
Somnolence			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
General disorders and administration site conditions			
Catheter Site Related Reaction			
subjects affected / exposed	4 / 20 (20.00%)		
occurrences (all)	5		
Catheter Site Pain			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Catheter Site Bruise			
subjects affected / exposed	3 / 20 (15.00%)		
occurrences (all)	3		
Fatigue			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences (all)	1		
Influenza Like Illness			
subjects affected / exposed	2 / 20 (10.00%)		
occurrences (all)	2		
Medical Device Site Reaction			

subjects affected / exposed occurrences (all) Vessel Puncture Site Pain subjects affected / exposed occurrences (all)	1 / 20 (5.00%) 1 1 / 20 (5.00%) 1		
Psychiatric disorders Sleep Disorder subjects affected / exposed occurrences (all)	 1 / 20 (5.00%) 1		
Gastrointestinal disorders Abdominal Discomfort subjects affected / exposed occurrences (all) Abdominal Distension subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Flatulence subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	 1 / 20 (5.00%) 1 1 / 20 (5.00%) 1 2 / 20 (10.00%) 2 1 / 20 (5.00%) 1 1 / 20 (5.00%) 1 1 / 20 (5.00%) 1		
Skin and subcutaneous tissue disorders Skin Irritation subjects affected / exposed occurrences (all)	 2 / 20 (10.00%) 2		
Musculoskeletal and connective tissue disorders Myalgia subjects affected / exposed occurrences (all)	 4 / 20 (20.00%) 4		

Metabolism and nutrition disorders Decreased Appetite subjects affected / exposed occurrences (all)	 1 / 20 (5.00%) 1		
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	 3 / 20 (15.00%) 3		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported