Clinical trial results:
Study Exploring the Supportive effect of Acarbose in weight Management - SESAM:
A 26-week, double-blind, randomized trial in participants with overweight or obesity investigating the added contribution of acarbose in EMP16 on efficacy, safety and tolerability

Summary

EudraCT number	2022-003320-40
Trial protocol	SE
Global end of trial date	13 December 2023

Results information

Result version number	v1 (current)
This version publication date	01 February 2025
First version publication date	01 February 2025

Trial information

Trial identification

Sponsor protocol code	EP-003

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05934110
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Empros Pharma AB
Sponsor organisation address	Nanna Svartz väg 4, Solna, Sweden, 17165
Public contact	Arvid Söderhäll, Empros Pharma AB, +46 070233363, arvid.soderhall@emprospharma.com
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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	13 December 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	13 December 2023
Global end of trial reached?	Yes
Global end of trial date	13 December 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To confirm the added effect of acarbose in EMP16-120/40 on efficacy after a 26-week period of oral treatment compared with MR-O and Conv-O

Protection of trial subjects:

Each potential study subject was given adequate verbal and written information before any study specific assessments were performed. The information included the objectives and the procedures of the study as well as any risks or inconvenience involved. It was emphasised that participation in the study was voluntary and that the subject could withdraw from participation at any time and for any reason, without any prejudice. All subjects were given the opportunity to ask questions about the study and were given sufficient time to consider participation before signing the ICF.
Before performing any studyrelated procedures, the ICF was signed and personally dated by the subject and by the Investigator. A copy of the subject information including the signed ICF was provided to the subject.
The ICF included information that data were to be recorded, collected and processed and could be transferred to European Economic Area (EEA) or non-EEA countries. In accordance with the EU general data protection regulation (GDPR), Regulation (EU) 2016/679, the data will not identify any persons taking part in the study.
The subject had the right to request access to their personal data and to request rectification of any data that were not correct and/or complete, in accordance with the EU GDPR Regulation (EU) 2016/679.

Background therapy:

N/A

Evidence for comparator:

N/A

Actual start date of recruitment	18 April 2023
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	Sweden: 320
Worldwide total number of subjects	320
EEA total number of subjects	320

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)	309
From 65 to 84 years	11
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants were recruited from CTC's database of volunteers, as well as from strategic marketing campaigns. Advertisements in social media and other media (newspapers, internet, radio, local distribution of flyers etc.) could be used to reach the target audience. The advertisement texts were approved by the independent ethics committee (IEC).

Pre-assignment

Screening details:

Screening (Visit 1) took place within 35 days prior to the first dose.
A total of 451 potential participants were screened, 320 were randomized and 277 completed the trial.

Period 1

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

Blinding implementation details:

This was a double-blind trial, and the allocation of treatments was not disclosed until clean file had been declared and the database had been locked.
EMP16-120/40, EMP16-60/20, MR-O, Conv-O (Alli® and Xenical®), and placebo capsules were identical in appearance. Alli® and Xenical® were recoated to match the EMP16, MR-O and placebo capsules.

Arms

Are arms mutually exclusive?	Yes
Arm title	EMP16-120/40

Arm description:

Participants were randomized to treatment with EMP16 120 mg orlistat/40 mg acarbose (referred to as EMP16-120/40).

Arm type	Experimental
Investigational medicinal product name	EMP16
Investigational medicinal product code	
Other name	Orlistat and acarbose
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

EMP16 is a modified release, fixed dose combination, of orlistat and acarbose.
Week 1 to 2: 60 mg orlistat/20 mg acarbose (1 capsule per day)
Week 3 to 4: 60 mg orlistat/20 mg acarbose (1 capsule TID)
Week 5 to 26: 60 mg O/20 mg A (2 capsules TID)

Arm title	MR orlistat

Arm description:

Participants were randomized to treatment with 120 mg modified release orlistat.

Arm type	Experimental
Investigational medicinal product name	MR-O (modified release orlistat)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

MR-O (120 mg orlistat) was the same as EMP16-120/40 but without the acarbose component in matching oral capsules.
Week 1 to 2: 60 mg MR-O (1 capsule per day)
Week 3 to 4: 60 mg MR-O (1 capsule TID)
Week 5 to 26: 60 mg MR-O (2 capsules TID)

Arm title	Conventional orlistat

Arm description:

Participants were randomized to treatment with 120 mg conventional orlistat.

Arm type	Experimental
Investigational medicinal product name	Conv-O (Conventional orlistat)
Investigational medicinal product code	
Other name	Alli®, Xenical®
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Conv-O was Alli® 60 mg during week 1 to 4 and Xenical® 120 mg from week 5 and onwards in matching oral capsules.
Week 1 to 2: 60 mg Conv-O (1 capsule per day)
Week 3 to 4: 60 mg Conv-O (1 capsule TID)
Week 5 to 26: 120 mg Conv-O plus placebo (1 capsule of each TID)

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Placebo was inert material in a matching capsule.
Week 5 to 26: Participants received 120 mg Conv-O plus placebo (1 capsule of each TID)

Arm title	EMP16-60/20

Arm description:

Participants were randomized to treatment with EMP16 60 mg orlistat/20 mg acarbose (referred to as EMP16-60/20).

Arm type	Experimental
Investigational medicinal product name	EMP16-60/20
Investigational medicinal product code	
Other name	Orlistat and acarbose
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

EMP16 is a modified release, fixed dose combination, of orlistat and acarbose. .
Week 1 to 2: 60 mg orlistat/20 mg acarbose (1 capsule per day)
Week 3 to 4: 60 mg orlistat/20 mg acarbose (1 capsule TID)
Week 5 to 26: 60 mg orlistat/20 mg acarbose plus placebo (1 capsule of each TID)

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Placebo was inert material in a matching capsule.
Week 5 to 26: Participants received 60 mg orlistat/20 mg acarbose plus placebo (1 capsule of each TID)

Arm title	Placebo

Arm description:	
Participants were randomized to treatment with placebo.	
Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Placebo was inert material in a matching capsule.
Week 1 to 2: Placebo (1 capsule per day)
Week 3 to 4: Placebo (1 capsule TID)
Week 5 to 26: Placebo (2 capsules TID)

Number of subjects in period 1	EMP16-120/40	MR orlistat	Conventional orlistat
Started	80	80	80
Completed	66	69	73
Not completed	14	11	7
Consent withdrawn by subject	11	10	5
Physician decision	-	-	1
Pregnancy	-	-	-
Lost to follow-up	3	1	1

Number of subjects in period 1	EMP16-60/20	Placebo
Started	40	40
Completed	36	33
Not completed	4	7
Consent withdrawn by subject	4	4
Physician decision	-	1
Pregnancy	-	1
Lost to follow-up	-	1

Baseline characteristics

Reporting groups	
Reporting group title	EMP16-120/40
Reporting group description:	
Participants were randomized to treatment with EMP16 120 mg orlistat/40 mg acarbose (referred to as EMP16-120/40).	
Reporting group title	MR orlistat
Reporting group description:	
Participants were randomized to treatment with 120 mg modified release orlistat.	
Reporting group title	Conventional orlistat
Reporting group description:	
Participants were randomized to treatment with 120 mg conventional orlistat.	
Reporting group title	EMP16-60/20
Reporting group description:	
Participants were randomized to treatment with EMP16 60 mg orlistat/20 mg acarbose (referred to as EMP16-60/20).	
Reporting group title	Placebo
Reporting group description:	
Participants were randomized to treatment with placebo.	

Reporting group values	EMP16-120/40	MR orlistat	Conventional orlistat
Number of subjects	80	80	80
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	44.9	46.0	46.1
standard deviation	± 11.1	± 10.6	± 10.7
Gender categorical Units: Subjects			
Female	41	38	40
Male	39	42	40

Reporting group values	EMP16-60/20	Placebo	Total
Number of subjects	40	40	320

Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	46.0	46.9	
standard deviation	± 11.6	± 11.0	-
Gender categorical Units: Subjects			
Female	20	20	159
Male	20	20	161

End points

End points reporting groups

Reporting group title	EMP16-120/40
Reporting group description:	
Participants were randomized to treatment with EMP16 120 mg orlistat/40 mg acarbose (referred to as EMP16-120/40).	

Reporting group title	MR orlistat
Reporting group description:	
Participants were randomized to treatment with 120 mg modified release orlistat.	

Reporting group title	Conventional orlistat
Reporting group description:	
Participants were randomized to treatment with 120 mg conventional orlistat.	

Reporting group title	EMP16-60/20
Reporting group description:	
Participants were randomized to treatment with EMP16 60 mg orlistat/20 mg acarbose (referred to as EMP16-60/20).	

Reporting group title	Placebo
Reporting group description:	
Participants were randomized to treatment with placebo.	

Primary: Relative (%) change from baseline in body weight at week 26

End point title	Relative (%) change from baseline in body weight at week 26
End point description:	
Weight was measured in kg (one decimal) without shoes and without thick clothes such as jumpers. Weight at Visit 2 was compared with weight at Visit 1 prior to randomization, to ensure that the participant was not meeting exclusion criteria. The mean±SD relative change from baseline in body weight at week 26 was -7.73±6.03% for the EMP16-120/40 group as compared to -5.78±5.29% and -5.13±4.59% for the MR-O and Conv-O groups, respectively. The treatment effect of EMP16-120/40 was statistically significant compared to both MR-O (-2.37%) and Conv-O (-2.64%).	
End point type	Primary
End point timeframe:	
Weight was measured at the screening visit and on week 0, 4, 10, 18 and 26.	

End point values	EMP16-120/40	MR orlistat	Conventional orlistat	EMP16-60/20
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	66	69	73	36
Units: percent				
arithmetic mean (standard deviation)				
Relative change from baseline (%) at week 26	7.73 (± 6.03)	5.78 (± 5.29)	5.13 (± 4.59)	5.12 (± 4.05)

End point values	Placebo			
Subject group type	Reporting group			
Number of subjects analysed	33			
Units: percent				
arithmetic mean (standard deviation)				
Relative change from baseline (%) at week 26	3.94 (± 5.97)			

Statistical analyses

Statistical analysis title	Relative (%) change from baseline in body weight

Statistical analysis description:

Relative (%) change from baseline in body weight at week 26, with EMP16-120/40 as compared to MR-O and Conv-O, respectively, was analyzed using mixed model repeated measures (MMRM).

Comparison groups	EMP16-120/40 v MR orlistat v Conventional orlistat v EMP16-60/20 v Placebo
Number of subjects included in analysis	277
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.0065 [1]
Method	Mixed models analysis

Notes:

[1] - EMP16 120/40 mg compared to MR orlistat 120 mg: p-value 0.0065
EMP16 120/40 mg compared to Conventional orlistat 120 mg: 0

Primary: Proportion of participants with ≥5% decrease in body weight at week 26

End point title	Proportion of participants with ≥5% decrease in body weight at week 26[2]

End point description:

The proportion of participants with ≥5% decrease in body weight at week 26 was 61% for the EMP16-120/40 group as compared to 51% and 48% in the MR-O and Conv-O groups, respectively. The differences between the EMP16-120/40 group and the MR-O and Conv-O groups were, however, not statistically significant.

End point type	Primary

End point timeframe:

Weight was measured at the screening visit and on week 0, 4, 10, 18 and 26.

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The proportion of participants with ≥5% decrease in body weight at week 26 was analyzed for the main treatment groups.

End point values	EMP16-120/40	MR orlistat	Conventional orlistat	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	66	69	73	
Units: percent				
number (not applicable)				
Proportion of participants (%) at week 26	61	51	48	

Statistical analyses

Statistical analysis title	Proportion of participants (%)
Statistical analysis description:	
The proportion of participants with ≥5% decrease in body weight at week 26 was analyzed pairwise using chi-square tests (i.e., separate analyses per comparison) for difference in sample proportions. Descriptive statistics was used to address this endpoint.	
Comparison groups	EMP16-120/40 v MR orlistat v Conventional orlistat
Number of subjects included in analysis	208
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	= 0.059 [3]
Method	Chi-squared

Notes:

[3] - Pairwise chi-square test p-value for the proportional difference to EMP16:
MR orlistat 120 mg: 0.0590
Conventional orlistat: 0.0862

Adverse events information

Timeframe for reporting adverse events:

AEs (including serious AEs [SAEs]) were collected from the start of IMP administration until the end-of-trial visit at week 26.

Adverse event reporting additional description:

The grading of the severity/intensity (grade 1 to grade 5) of AEs followed the common terminology criteria for AEs (CTCAE) v5.0. AEs were assessed as unlikely, possibly or probably related to the IMP. Fecal incontinence and/or oily spotting were documented as AEs of special interest (AESI) and the level of discomfort was rated by the participants.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	EMP16-120/40

Reporting group description:

Participants were randomized to treatment with EMP16 120 mg orlistat/40 mg acarbose (referred to as EMP16-120/40).
The participants followed a dose escalation schedule:
- Week 1 to 2: 60 mg orlistat/20 mg acarbose (1 capsule per day)
- Week 3 to 4: 60 mg orlistat/20 mg acarbose (1 capsule TID)
- Week 5 to 26: 60 mg orlistat/20 mg acarbose (2 capsules TID)

Reporting group title	MR orlistat

Reporting group description:

Participants were randomized to treatment with 120 mg orlistat.
The participants followed a dose escalation schedule:
- Week 1 to 2: 60 mg MR-O (1 capsule per day)
- Week 3 to 4: 60 mg MR-O (1 capsule TID)
- Week 5 to 26: 60 mg MR-O (2 capsules TID)

Reporting group title	Conventional orlistat

Reporting group description:

Participants were randomized to treatment with 120 mg orlistat.
The participants followed a dose escalation schedule:
- Week 1 to 2: 60 mg Conv-O (1 capsule per day)
- Week 3 to 4: 60 mg Conv-O (1 capsule TID)
- Week 5 to 26: 120 mg Conv-O plus placebo (1 capsule of each TID)

Reporting group title	EMP16-60/20

Reporting group description:

Participants were randomized to treatment with EMP16 60 mg orlistat/20 mg acarbose (referred to as EMP16-60/20).
The participants followed a dose escalation schedule:
- Week 1 to 2: 60 mg orlistat/20 mg acarbose (1 capsule per day)
- Week 3 to 4: 60 mg orlistat/20 mg acarbose (1 capsule TID)
- Week 5 to 26: 60 mg orlistat/20 mg acarbose plus placebo (1 capsule of each TID)

Reporting group title	Placebo

Reporting group description:

Participants were randomized to treatment with placebo.
The participants followed a dose escalation schedule:
- Week 1 to 2: Placebo (1 capsule per day)
- Week 3 to 4: Placebo (1 capsule TID)
- Week 5 to 26: Placebo (2 capsules TID)

Serious adverse events	EMP16-120/40	MR orlistat	Conventional orlistat
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Serious adverse events	EMP16-60/20	Placebo	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	EMP16-120/40	MR orlistat	Conventional orlistat
Total subjects affected by non-serious adverse events			
subjects affected / exposed	78 / 80 (97.50%)	73 / 80 (91.25%)	75 / 80 (93.75%)
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 80 (2.50%)	0 / 80 (0.00%)	3 / 80 (3.75%)
occurrences (all)	3	0	3
Hypotension			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Surgical and medical procedures			
Dental operation			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Eye operation			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	2
Foot operation			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Hip surgery			

subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Knee operation			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Limb operation			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Nail operation			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Shoulder operation			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Tooth extraction			
subjects affected / exposed	1 / 80 (1.25%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	1	1	0
Wisdom teeth removal			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Cyst			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	2	0
Exercise tolerance decreased			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	3 / 80 (3.75%)
occurrences (all)	1	0	3
Feeling cold			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Hunger			

subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Inflammation			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 80 (0.00%)	2 / 80 (2.50%)	0 / 80 (0.00%)
occurrences (all)	0	2	0
Pyrexia			
subjects affected / exposed	1 / 80 (1.25%)	2 / 80 (2.50%)	0 / 80 (0.00%)
occurrences (all)	1	2	0
Sensation of foreign body			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Immunisation reaction			
subjects affected / exposed	2 / 80 (2.50%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	2	0	0
Seasonal allergy			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			
dysmenorrhoea			
subjects affected / exposed	1 / 80 (1.25%)	3 / 80 (3.75%)	1 / 80 (1.25%)
occurrences (all)	1	3	1
Heavy menstrual bleeding			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Intermenstrual bleeding			

subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
menstruation delayed			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Scrotal mass			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
dyspnoea			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	2 / 80 (2.50%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	2	0	1
Psychiatric disorders			
Acute stress disorder			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Depressed mood			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Insomnia			

subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Sleep disorder			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Stress			
subjects affected / exposed	0 / 80 (0.00%)	2 / 80 (2.50%)	1 / 80 (1.25%)
occurrences (all)	0	2	1
Investigations			
alanin			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Blood glucose decreased			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
blood glucose increased			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Blood pressure increased			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Heart rate decreased			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Hepatic enzyme increased			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	2 / 80 (2.50%)
occurrences (all)	0	0	2
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Ankle fracture			

subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Arthropod sting			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Bite			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Carbon monoxide poisoning			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Fibula fracture			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Joint dislocation			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Limb injury			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Muscle strain			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
post-traumatic pain			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Chest discomfort			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	3 / 80 (3.75%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	3	0	1
Headache			
subjects affected / exposed	13 / 80 (16.25%)	7 / 80 (8.75%)	8 / 80 (10.00%)
occurrences (all)	13	8	11
Migraine			
subjects affected / exposed	1 / 80 (1.25%)	3 / 80 (3.75%)	1 / 80 (1.25%)
occurrences (all)	1	4	1
Nerve compression			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Sciatica			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Aural polyp			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
ear pain			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Motion sickness			

subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	3 / 80 (3.75%)	0 / 80 (0.00%)	3 / 80 (3.75%)
occurrences (all)	3	0	3
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	13 / 80 (16.25%)	9 / 80 (11.25%)	5 / 80 (6.25%)
occurrences (all)	15	9	7
Abdominal pain			
subjects affected / exposed	5 / 80 (6.25%)	6 / 80 (7.50%)	5 / 80 (6.25%)
occurrences (all)	7	6	5
Abdominal pain upper			
subjects affected / exposed	4 / 80 (5.00%)	5 / 80 (6.25%)	6 / 80 (7.50%)
occurrences (all)	7	5	6
Abnormal faeces			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Anal incontinence			
subjects affected / exposed	19 / 80 (23.75%)	10 / 80 (12.50%)	11 / 80 (13.75%)
occurrences (all)	22	12	11
Breath odour			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	1 / 80 (1.25%)	1 / 80 (1.25%)	2 / 80 (2.50%)
occurrences (all)	1	1	2
defecation urgency			
subjects affected / exposed	3 / 80 (3.75%)	4 / 80 (5.00%)	8 / 80 (10.00%)
occurrences (all)	3	5	11
Diarrhoea			

subjects affected / exposed	50 / 80 (62.50%)	51 / 80 (63.75%)	53 / 80 (66.25%)
occurrences (all)	57	67	58
Dry mouth			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	2 / 80 (2.50%)
occurrences (all)	0	0	2
Dyspepsia			
subjects affected / exposed	2 / 80 (2.50%)	2 / 80 (2.50%)	1 / 80 (1.25%)
occurrences (all)	3	2	1
Eructation			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
feces discolored			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
feces hard			
subjects affected / exposed	2 / 80 (2.50%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	2	1	0
Flatulence			
subjects affected / exposed	46 / 80 (57.50%)	24 / 80 (30.00%)	15 / 80 (18.75%)
occurrences (all)	49	24	15
Food poisoning			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	1 / 80 (1.25%)
occurrences (all)	0	1	1
Frequent bowel movements			
subjects affected / exposed	1 / 80 (1.25%)	1 / 80 (1.25%)	1 / 80 (1.25%)
occurrences (all)	1	1	1
gastroesophageal reflux disease			
subjects affected / exposed	2 / 80 (2.50%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	2	1	0
hematochezia			
subjects affected / exposed	2 / 80 (2.50%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	2	0	0
hemorrhoids			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Nausea			

subjects affected / exposed	4 / 80 (5.00%)	1 / 80 (1.25%)	5 / 80 (6.25%)
occurrences (all)	4	1	5
Proctalgia			
subjects affected / exposed	0 / 80 (0.00%)	2 / 80 (2.50%)	1 / 80 (1.25%)
occurrences (all)	0	2	1
Rectal discharge			
subjects affected / exposed	33 / 80 (41.25%)	22 / 80 (27.50%)	25 / 80 (31.25%)
occurrences (all)	38	26	29
Steatorrhoea			
subjects affected / exposed	15 / 80 (18.75%)	4 / 80 (5.00%)	10 / 80 (12.50%)
occurrences (all)	15	4	10
Toothache			
subjects affected / exposed	3 / 80 (3.75%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	3	0	1
Vomiting			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	1	0	1
Hepatobiliary disorders			
biliary colic			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	2	0	1
Erythema			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Hyperhidrosis			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	2	0	1
Rash			

subjects affected / exposed	1 / 80 (1.25%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	1	1	0
Urticaria			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
hematuria			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Micturition urgency			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Renal colic			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
hyperglycemia			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 80 (2.50%)	1 / 80 (1.25%)	2 / 80 (2.50%)
occurrences (all)	2	1	2
Back pain			
subjects affected / exposed	2 / 80 (2.50%)	4 / 80 (5.00%)	1 / 80 (1.25%)
occurrences (all)	2	4	1
Bursitis			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Coccydynia			

subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Muscle spasms			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	2 / 80 (2.50%)
occurrences (all)	0	0	2
Myalgia			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	2	0	1
Osteoarthritis			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Plantar fasciitis			
subjects affected / exposed	0 / 80 (0.00%)	2 / 80 (2.50%)	1 / 80 (1.25%)
occurrences (all)	0	2	1
Rotator cuff syndrome			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Tendonitis			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Torticollis			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Borrelia infection			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	2	0	0
Bronchitis			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
COVID-19			
subjects affected / exposed	0 / 80 (0.00%)	4 / 80 (5.00%)	1 / 80 (1.25%)
occurrences (all)	0	4	1

Conjunctivitis			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	1 / 80 (1.25%)
occurrences (all)	0	1	1
Diverticulitis			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Ear infection			
subjects affected / exposed	0 / 80 (0.00%)	2 / 80 (2.50%)	0 / 80 (0.00%)
occurrences (all)	0	2	0
Gastroenteritis			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis viral			
subjects affected / exposed	2 / 80 (2.50%)	0 / 80 (0.00%)	3 / 80 (3.75%)
occurrences (all)	2	0	3
Hand-foot-and-mouth disease			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	1	0	1
Herpes zoster			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	3 / 80 (3.75%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	3	0	1
Localised infection			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Lyme disease			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	2 / 80 (2.50%)
occurrences (all)	1	0	2
Nasopharyngitis			
subjects affected / exposed	23 / 80 (28.75%)	32 / 80 (40.00%)	26 / 80 (32.50%)
occurrences (all)	25	40	31
Oral herpes			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0

Otitis media			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	1 / 80 (1.25%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	1	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Respiratory tract infection viral			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	1 / 80 (1.25%)
occurrences (all)	0	1	1
Skin infection			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	0 / 80 (0.00%)
occurrences (all)	1	0	0
Tonsillitis			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	2 / 80 (2.50%)
occurrences (all)	0	0	2
Tooth infection			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	1 / 80 (1.25%)
occurrences (all)	0	1	1
Urinary tract infection			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	1 / 80 (1.25%)	4 / 80 (5.00%)	1 / 80 (1.25%)
occurrences (all)	1	4	1
Food craving			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Gout			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	2	0
Hyperinsulinaemia			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Hyperlipidaemia			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Hypertriglyceridaemia			
subjects affected / exposed	1 / 80 (1.25%)	0 / 80 (0.00%)	2 / 80 (2.50%)
occurrences (all)	1	0	2
Increased appetite			
subjects affected / exposed	0 / 80 (0.00%)	1 / 80 (1.25%)	0 / 80 (0.00%)
occurrences (all)	0	1	0
Iron deficiency			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 80 (0.00%)	0 / 80 (0.00%)	1 / 80 (1.25%)
occurrences (all)	0	0	1

Non-serious adverse events	EMP16-60/20	Placebo	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	36 / 40 (90.00%)	34 / 40 (85.00%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 40 (5.00%)	4 / 40 (10.00%)	
occurrences (all)	2	4	
Hypotension			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Surgical and medical procedures			
Dental operation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Eye operation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Foot operation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Hip surgery			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Knee operation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Limb operation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Nail operation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Shoulder operation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Tooth extraction			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Wisdom teeth removal			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			

Cyst			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Exercise tolerance decreased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	1 / 40 (2.50%)	3 / 40 (7.50%)	
occurrences (all)	1	3	
Feeling cold			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Hunger			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Inflammation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Malaise			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	1 / 40 (2.50%)	4 / 40 (10.00%)	
occurrences (all)	1	4	
Sensation of foreign body			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Thirst			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Immunisation reaction			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Seasonal allergy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
dysmenorrhoea			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Heavy menstrual bleeding			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Intermenstrual bleeding			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
menstruation delayed			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Scrotal mass			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
dyspnoea			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Nasal congestion			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			

Acute stress disorder			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Anxiety			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Depressed mood			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Depression			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Insomnia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Sleep disorder			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Stress			
subjects affected / exposed	0 / 40 (0.00%)	2 / 40 (5.00%)	
occurrences (all)	0	2	
Investigations			
alanin			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Blood glucose decreased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
blood glucose increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Blood pressure increased			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Heart rate decreased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Ankle fracture			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Arthropod sting			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Bite			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Carbon monoxide poisoning			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Fall			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Fibula fracture			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Joint dislocation			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Ligament sprain			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Limb injury			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	
occurrences (all)	1	1	
Muscle strain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
post-traumatic pain			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	
occurrences (all)	1	1	
Road traffic accident			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Cardiac disorders			
Chest discomfort			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Palpitations			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	7 / 40 (17.50%)	6 / 40 (15.00%)	
occurrences (all)	9	8	
Migraine			
subjects affected / exposed	1 / 40 (2.50%)	2 / 40 (5.00%)	
occurrences (all)	1	2	
Nerve compression			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Sciatica			

subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Somnolence			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Syncope			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Aural polyp			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
ear pain			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Motion sickness			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Vertigo			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	4 / 40 (10.00%)	5 / 40 (12.50%)	
occurrences (all)	4	5	
Abdominal pain			
subjects affected / exposed	5 / 40 (12.50%)	2 / 40 (5.00%)	
occurrences (all)	6	3	
Abdominal pain upper			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Abnormal faeces			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Anal incontinence			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Breath odour			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	2 / 40 (5.00%)	2 / 40 (5.00%)	
occurrences (all)	2	2	
defecation urgency			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Diarrhoea			
subjects affected / exposed	23 / 40 (57.50%)	10 / 40 (25.00%)	
occurrences (all)	24	11	
Dry mouth			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Eructation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
feces discolored			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
feces hard			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Flatulence			
subjects affected / exposed	23 / 40 (57.50%)	12 / 40 (30.00%)	
occurrences (all)	24	14	
Food poisoning			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Frequent bowel movements			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	
occurrences (all)	1	1	
gastroesophageal reflux disease			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
hematochezia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
hemorrhoids			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	
occurrences (all)	2	1	
Proctalgia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Rectal discharge			
subjects affected / exposed	10 / 40 (25.00%)	2 / 40 (5.00%)	
occurrences (all)	13	2	
Steatorrhoea			
subjects affected / exposed	4 / 40 (10.00%)	0 / 40 (0.00%)	
occurrences (all)	4	0	
Toothache			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Vomiting			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			
biliary colic			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	

Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 40 (0.00%)	2 / 40 (5.00%)	
occurrences (all)	0	2	
Erythema			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Hyperhidrosis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Pruritus			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Rash			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Urticaria			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Calculus urinary			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
hematuria			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Micturition urgency			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	2	
Pollakiuria			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Renal colic			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Endocrine disorders			

hyperglycemia			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 40 (0.00%)	2 / 40 (5.00%)	
occurrences (all)	0	2	
Back pain			
subjects affected / exposed	0 / 40 (0.00%)	5 / 40 (12.50%)	
occurrences (all)	0	5	
Bursitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Coccydynia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Muscle spasms			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Myalgia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Osteoarthritis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Plantar fasciitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Rotator cuff syndrome			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Tendonitis			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Torticollis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Borrelia infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Bronchitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
COVID-19			
subjects affected / exposed	2 / 40 (5.00%)	1 / 40 (2.50%)	
occurrences (all)	2	1	
Conjunctivitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Diverticulitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Ear infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Gastroenteritis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis viral			
subjects affected / exposed	0 / 40 (0.00%)	2 / 40 (5.00%)	
occurrences (all)	0	2	
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Herpes zoster			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	

Influenza			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Localised infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	
occurrences (all)	0	1	
Lyme disease			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	16 / 40 (40.00%)	12 / 40 (30.00%)	
occurrences (all)	18	18	
Oral herpes			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Otitis media			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection viral			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Rhinitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Sinusitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Skin infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	

Tonsillitis			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	
occurrences (all)	1	1	
Tooth infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Food craving			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Gout			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Hyperinsulinaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Hyperlipidaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Hypertriglyceridaemia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Increased appetite			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Iron deficiency			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	
occurrences (all)	0	0	

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

N/A

Notes: