



Clinical trial results:

A Randomised Double-Blinded Placebo-Controlled Trial to Assess the Efficacy and Safety of Scopolamine Compared to Placebo in Individuals with Bipolar Disorder who are Experiencing a Depressive Episode (SCOPE-BD)

Summary

EudraCT number	2017-003112-39
Trial protocol	IE
Global end of trial date	22 February 2024

Results information

Result version number	v1 (current)
This version publication date	09 March 2025
First version publication date	09 March 2025

Trial information

Trial identification

Sponsor protocol code	NUIG-2017-002
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04211961
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University of Galway
Sponsor organisation address	University Road, Galway City, Ireland,
Public contact	Dr. Brian Hallahan, Department of Psychiatry, Clinical Science Institute, University of Galway, Galway, Ireland, brian.hallahan@universityofgalway.ie
Scientific contact	Dr. Brian Hallahan, Department of Psychiatry, Clinical Science Institute, University of Galway, Galway, Ireland, brian.hallahan@universityofgalway.ie

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	22 August 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 February 2024
Global end of trial reached?	Yes
Global end of trial date	22 February 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to investigate the efficacy and safety of IV Scopolamine, compared to placebo, in reducing severity of depression in individuals with bipolar disorder who are experiencing a depressive episode of at least moderate severity.

Protection of trial subjects:

The SCOPE-BD trial was approved by Galway University Hospital Clinical Research Ethics Committee. This study was conducted in compliance with the protocol, International Conference on Harmonization – Good Clinical Practice (ICH-GCP) and any applicable regulatory requirements including the archiving of essential documents. The PI was responsible for obtaining informed consent from each patient or legal representative and for obtaining the appropriate signatures on the Informed Consent Document (ICD) prior to the performance of any protocol procedures and before administration of study drug. The PI provided a copy of the signed ICD to the patient, and a copy was maintained at the investigative site.

A properly executed, signed ICD was obtained from each patient. Eligible patients were only included in the trial after providing written informed consent. Informed consent was obtained prior to conducting any trial specific procedures. Upon providing consent, the informed consent form (ICF) was signed and dated by the subject, and the investigator who administered the ICF. The complete original ICF was filed by the site in the site file, a copy of the ICF was given to the participant and a copy was filed in the patients notes. An additional consent was obtained for bio-banking samples; this was pre-approved by the approving Ethics Committee.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 December 2019
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	Ireland: 55
Worldwide total number of subjects	55
EEA total number of subjects	55

Notes:

Subjects enrolled per age group

In utero	0
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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)	50
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment Period: 23 March 2021 to 22 February 2024.

The study has one location - University Hospital Galway, Galway, Ireland.

Pre-assignment

Screening details:

Patients were eligible for participation if they carried diagnosis of Bipolar Disorder by DSM-V criteria and were experiencing an episode of depression of at least moderate severity at Visit 1 (Screening) and Visit 2 based on clinical interview by a trained clinician and a Hamilton Depression Rating Scale (HDRS) score ≥ 14 .

Pre-assignment period milestones

Number of subjects started	55
Number of subjects completed	50

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Not eligible for randomisation: 5
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Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Patients randomised to the Placebo arm received an intravenous infusion of saline at each study visit (Visits 3,4,5)

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

Dosage and administration details:

100mL saline infused over 15 minutes

Arm title	Scopolamine
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Arm description:

Patients randomised to Scopolamine received an infusion of Scopolamine 4 µg/kg in 100mL saline over 15 minutes at each study visit (Visits 3,4,5)

Arm type	Experimental
Investigational medicinal product name	Scopolamine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

4 µg/kg in 100mL saline infused over 15 minutes

Number of subjects in period 1^[1]	Placebo	Scopolamine
Started	24	26
Completed	24	26

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Of the 55 participants who consented, 5 were withdrawn pre-randomisation. Fifty participants were eventually randomised into the SCOPE-BD trial.

Enrolled patients underwent a placebo treatment at Visit 2 and were eligible for randomisation at Visit 3 only if their depressive symptoms were still at least moderate in severity.

Period 2

Period 2 title	After last treatment (Visit 6)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 100mL saline infused over 15 minutes	
Arm title	Scopolamine
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Scopolamine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

4 µg/kg in 100mL saline infused over 15 minutes

Number of subjects in period 2	Placebo	Scopolamine
Started	24	26
Completed	24	24
Not completed	0	2
Adverse event, serious fatal	-	1
Consent withdrawn by subject	-	1

Period 3

Period 3 title	Followup (Visit 7)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo
Arm description: -	
Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
100mL saline infused over 15 minutes	
Arm title	Scopolamine
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

100mL saline infused over 15 minutes

Investigational medicinal product name	Scopolamine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

4 µg/kg in 100mL saline infused over 15 minutes

Number of subjects in period 3	Placebo	Scopolamine
Started	24	24
Completed	24	23
Not completed	0	1
Lost to follow-up	-	1

Baseline characteristics

Reporting groups

Reporting group title	Placebo
Reporting group description:	
Patients randomised to the Placebo arm received an intravenous infusion of saline at each study visit (Visits 3,4,5)	
Reporting group title	Scopolamine
Reporting group description:	
Patients randomised to Scopolamine received an infusion of Scopolamine 4 µg/kg in 100mL saline over 15 minutes at each study visit (Visits 3,4,5)	

Reporting group values	Placebo	Scopolamine	Total
Number of subjects	24	26	50
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)	22	23	45
From 65-84 years	2	3	5
85 years and over	0	0	0
Age continuous			
Age in years at baseline			
Units: years			
median	53	42	
inter-quartile range (Q1-Q3)	46 to 57	37 to 50	-
Gender categorical			
Units: Subjects			
Female	15	11	26
Male	9	15	24
Race			
Units: Subjects			
Asian	0	1	1
White	23	24	47
Hispanic/LatinX	1	1	2
Occupational status			
Occupational status at baseline			
Units: Subjects			
Employed full-time for pay	4	2	6
Employed part-time for pay	1	5	6
Full-time student	2	1	3
Homemaker	2	1	3
Leave of absence for medical reasons	2	4	6

Retired	3	1	4
Unemployed <6months, expects to work	0	2	2
Unemployed <6months, does not expect to work	1	1	2
Unemployed >=6 months, expects to work	2	5	7
Unemployed >=6months, does not expect to work	7	4	11
Educational status			
Educational status at baseline			
Units: Subjects			
College graduate	11	5	16
Graduate professional training (Masters or above)	6	7	13
High school graduate	3	6	9
Junioo high school (7th,8th,9th)	0	1	1
Some college or technical school (at least 1yr)	3	5	8
Some High School (10th,11th)	1	2	3
Relationship status			
Relationship status at baseline			
Units: Subjects			
Divorced	3	3	6
Long-term relationship	4	2	6
Married	7	4	11
Single	10	17	27
Socioeconomic status			
Socioeconomic status at baseline			
Units: Subjects			
Machine operators, semiskilled workers	3	9	12
Major business and professional	1	1	2
Medium business, minor professional, technical	8	6	14
Skilled craftsmen, clerical, sales workers	7	4	11
Unskilled labourers, menial service workers	5	6	11
Handedness			
Units: Subjects			
Right-handed	20	23	43
Left-handed	3	1	4
Ambidextrous	1	2	3
Psychosis			
History of Psychosis at baseline			
Units: Subjects			
Yes	10	13	23
No	14	13	27
Rapid cycling			
Units: Subjects			
Yes	2	3	5
No	22	23	45
Smoker			
Units: Subjects			

Yes	8	9	17
No	16	17	33
Alcohol use Units: Subjects			
Yes	7	7	14
No	17	19	36
Alcohol dependence Units: Subjects			
Yes	3	5	8
No	21	21	42
Cannabis use Units: Subjects			
Yes	3	3	6
No	21	23	44

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Patients randomised to the Placebo arm received an intravenous infusion of saline at each study visit (Visits 3,4,5)	
Reporting group title	Scopolamine
Reporting group description: Patients randomised to Scopolamine received an infusion of Scopolamine 4 µg/kg in 100mL saline over 15 minutes at each study visit (Visits 3,4,5)	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Scopolamine
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	
Reporting group title	Scopolamine
Reporting group description: -	

Primary: Hamilton Depression Rating Scale (HDRS) score

End point title	Hamilton Depression Rating Scale (HDRS) score
End point description: Score on Hamilton Depression Rating Scale (HDRS)	
End point type	Primary
End point timeframe: At time of last treatment (Visit 6) about 2 weeks after randomisation, and at time of followup (Visit 7) about one month after randomisation	

End point values	Placebo	Scopolamine	Placebo	Scopolamine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	23
Units: units on a scale				
median (inter-quartile range (Q1-Q3))	12 (7 to 15.5)	13 (10.8 to 17)	9 (5 to 14)	12 (10 to 15)

Statistical analyses

Statistical analysis title	Wilcoxin Rank Sum Test
Comparison groups	Scopolamine v Placebo

Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	Wilcoxon Rank Sum Test
Comparison groups	Placebo v Scopolamine
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2
Method	Wilcoxon (Mann-Whitney)

Secondary: Montgomery and Asberg Depression Scale (MADRS)

End point title	Montgomery and Asberg Depression Scale (MADRS)
End point description:	
End point type	Secondary
End point timeframe:	
At time of last treatment (Visit 6) about 2 weeks after randomisation, and at time of followup (Visit 7) about one month after randomisation	

End point values	Placebo	Scopolamine	Placebo	Scopolamine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	23
Units: units on a scale				
median (inter-quartile range (Q1-Q3))	14 (9 to 20)	16 (10 to 27)	11 (6 to 20)	14 (12 to 18)

Statistical analyses

Statistical analysis title	Wilcoxin Rank Sum Test
Comparison groups	Placebo v Scopolamine
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6
Method	Wilcoxon (Mann-Whitney)

Statistical analysis title	Wilcoxin Rank Sum Test
Comparison groups	Placebo v Scopolamine
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3
Method	Wilcoxon (Mann-Whitney)

Secondary: Profile of Overall Mood State (POMS)

End point title	Profile of Overall Mood State (POMS)
End point description:	
End point type	Secondary
End point timeframe:	
At time of last infusion (Visit 6)	

End point values	Placebo	Scopolamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	23		
Units: units on a scale				
median (inter-quartile range (Q1-Q3))	27 (9 to 51)	41 (16 to 93)		

Statistical analyses

Statistical analysis title	Wilcoxin Rank Sum Test
Comparison groups	Placebo v Scopolamine
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2
Method	Wilcoxon (Mann-Whitney)

Secondary: Remission of depressive episode

End point title	Remission of depressive episode
End point description:	
Remission defined as occurring when individual has HDRS score ≤ 7 and MADRS score < 6	
End point type	Secondary
End point timeframe:	
Assessed at time of last treatment (Visit 6) about 2 weeks after randomisation, and at at time of Followup visit (Visit 7) about one month after randomisation	

End point values	Placebo	Scopolamine	Placebo	Scopolamine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	23
Units: subjects	2	2	4	1

Statistical analyses

Statistical analysis title	Fisher's Exact Test
Comparison groups	Placebo v Scopolamine
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.9
Method	Fisher exact

Statistical analysis title	Fisher's Exact Test
Comparison groups	Scopolamine v Placebo
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3
Method	Fisher exact

Secondary: Response of depressive episode

End point title	Response of depressive episode
End point description: Response defined as a 50% reduction in MADRS score at assessment visit, compared to Visit 3 (randomisation visit)	
End point type	Secondary
End point timeframe: At time of last treatment visit (Visit 6), about two weeks after randomisation, and at time of Followup (visit 7) about a month after randomisation.	

End point values	Placebo	Scopolamine	Placebo	Scopolamine
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	24	24	24	23
Units: subjects	9	7	7	6

Statistical analyses

Statistical analysis title	Chi-Squared test
Comparison groups	Placebo v Scopolamine
Number of subjects included in analysis	48
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5
Method	Chi-squared

Statistical analysis title	Chi-Squared test
Comparison groups	Placebo v Scopolamine
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8
Method	Chi-squared

Secondary: Psychiatric inpatient admission

End point title	Psychiatric inpatient admission
End point description:	
End point type	Secondary
End point timeframe:	
During study participation (Visits 2 through 7)	

End point values	Placebo	Scopolamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	23		
Units: subjects	1	2		

Statistical analyses

Statistical analysis title	Fisher's Exact Test
Comparison groups	Placebo v Scopolamine
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.9
Method	Fisher exact

Secondary: Introduction of new antidepressant

End point title	Introduction of new antidepressant
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End point description:

End point type	Secondary
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End point timeframe:

During study participation, about a month.

End point values	Placebo	Scopolamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	23		
Units: subjects	2	3		

Statistical analyses

Statistical analysis title	Fisher's Exact Test
Comparison groups	Placebo v Scopolamine
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.9
Method	Fisher exact

Secondary: Increase in dose of existing antidepressant

End point title	Increase in dose of existing antidepressant
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End point description:

End point type	Secondary
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End point timeframe:

At any time during study participation, about a month.

End point values	Placebo	Scopolamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	23		
Units: subjects	4	4		

Statistical analyses

Statistical analysis title	Fisher's Exact Test
Comparison groups	Placebo v Scopolamine
Number of subjects included in analysis	47
Analysis specification	Pre-specified
Analysis type	superiority
P-value	> 0.9
Method	Fisher exact

Secondary: Occurrence of (hypo)manic episode

End point title	Occurrence of (hypo)manic episode
End point description:	
Defined as score of >6 on the Young Mania Rating Scale (YMRS)	
End point type	Secondary
End point timeframe:	
At any time during Randomisation (Visit 3) through Followup (Visit 7) about a month after randomisation	

End point values	Placebo	Scopolamine		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	23		
Units: subjects	0	1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Any time from randomisation to followup visit, about a month

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.0
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Reporting groups

Reporting group title	Placebo
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Reporting group description: -

Reporting group title	Scopolamine
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Reporting group description: -

Serious adverse events	Placebo	Scopolamine	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 24 (4.17%)	3 / 26 (11.54%)	
number of deaths (all causes)	0	1	
number of deaths resulting from adverse events	0	1	
Psychiatric disorders			
Depressed Mood leading to hospitalisation	Additional description: Depressed Mood leading to hospitalisation		
subjects affected / exposed	1 / 24 (4.17%)	1 / 26 (3.85%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suspected suicide	Additional description: Suspected suicide		
subjects affected / exposed	0 / 24 (0.00%)	1 / 26 (3.85%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hospitalisation - due to psychosocial stressors	Additional description: Hospitalisation - due to psychosocial stressors		
subjects affected / exposed	0 / 24 (0.00%)	1 / 26 (3.85%)	
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: 0 %

Non-serious adverse events	Placebo	Scopolamine	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 24 (58.33%)	25 / 26 (96.15%)	
Vascular disorders			
Flushing			
subjects affected / exposed	1 / 24 (4.17%)	1 / 26 (3.85%)	
occurrences (all)	1	1	
General disorders and administration site conditions			
Bruise from venipuncture	Additional description: Bruise from venipuncture		
subjects affected / exposed	1 / 24 (4.17%)	0 / 26 (0.00%)	
occurrences (all)	1	0	
Fatigue	Additional description: Fatigue		
subjects affected / exposed	5 / 24 (20.83%)	3 / 26 (11.54%)	
occurrences (all)	5	3	
Knot in throat	Additional description: Knot in throat		
subjects affected / exposed	0 / 24 (0.00%)	1 / 26 (3.85%)	
occurrences (all)	0	1	
Spaciness	Additional description: Feeling 'spacey'		
subjects affected / exposed	1 / 24 (4.17%)	1 / 26 (3.85%)	
occurrences (all)	1	1	
Shivering	Additional description: Shivering		
subjects affected / exposed	0 / 24 (0.00%)	1 / 26 (3.85%)	
occurrences (all)	0	1	
Thirst	Additional description: Thirst		
subjects affected / exposed	0 / 24 (0.00%)	4 / 26 (15.38%)	
occurrences (all)	0	6	
Reproductive system and breast disorders			
Pain from endometriosis	Additional description: Pain from endometriosis		
subjects affected / exposed	1 / 24 (4.17%)	0 / 26 (0.00%)	
occurrences (all)	1	0	
Pain in tissue beside hip	Additional description: Pain in tissue beside hip		
subjects affected / exposed	1 / 24 (4.17%)	0 / 26 (0.00%)	
occurrences (all)	1	0	
Respiratory, thoracic and mediastinal disorders			

Dry throat subjects affected / exposed occurrences (all)	Additional description: Dry throat		
	0 / 24 (0.00%) 0	1 / 26 (3.85%) 1	
Sore throat subjects affected / exposed occurrences (all)	Additional description: Sore throat		
	1 / 24 (4.17%) 1	1 / 26 (3.85%) 1	
Pain on Side of throat subjects affected / exposed occurrences (all)	Additional description: Pain on Side of throat		
	0 / 24 (0.00%) 0	1 / 26 (3.85%) 1	
Respiratory Problems subjects affected / exposed occurrences (all)	Additional description: Respiratory Problems		
	2 / 24 (8.33%) 2	0 / 26 (0.00%) 0	
Wheeziness subjects affected / exposed occurrences (all)	Additional description: Wheeziness		
	1 / 24 (4.17%) 1	0 / 26 (0.00%) 0	
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all) feeling panicky subjects affected / exposed occurrences (all) Feeling "on edge" subjects affected / exposed occurrences (all) Feeling "confused and scattered" subjects affected / exposed occurrences (all)	Additional description: Anxiety		
	0 / 24 (0.00%) 0	1 / 26 (3.85%) 1	
	Additional description: feeling panicky		
	0 / 24 (0.00%) 0	1 / 26 (3.85%) 1	
	Additional description: Feeling "on edge"		
	0 / 24 (0.00%) 0	1 / 26 (3.85%) 1	
Investigations Colonoscopy subjects affected / exposed occurrences (all) Elevated blood sugar levels subjects affected / exposed occurrences (all)	Additional description: Feeling "confused and scattered"		
	0 / 24 (0.00%) 0	1 / 26 (3.85%) 1	
	Additional description: Colonoscopy		
	1 / 24 (4.17%) 1	0 / 26 (0.00%) 0	
	Additional description: Elevated blood sugar levels		
	1 / 24 (4.17%) 1	0 / 26 (0.00%) 0	
Nervous system disorders			

Dizziness subjects affected / exposed occurrences (all)	Additional description: Dizziness	
	1 / 24 (4.17%) 1	19 / 26 (73.08%) 25
Drowsiness subjects affected / exposed occurrences (all)	Additional description: Drowsiness	
	0 / 24 (0.00%) 0	8 / 26 (30.77%) 11
Headache subjects affected / exposed occurrences (all)	Additional description: Headache	
	5 / 24 (20.83%) 7	7 / 26 (26.92%) 7
Giddiness subjects affected / exposed occurrences (all)	Additional description: Giddiness	
	0 / 24 (0.00%) 0	1 / 26 (3.85%) 1
Shakiness subjects affected / exposed occurrences (all)	Additional description: Shakiness	
	0 / 24 (0.00%) 0	1 / 26 (3.85%) 1
Restless legs syndrome subjects affected / exposed occurrences (all)	Additional description: Restless legs syndrome	
	1 / 24 (4.17%) 1	0 / 26 (0.00%) 0
Light-Headedness subjects affected / exposed occurrences (all)	Additional description: Light-Headedness	
	0 / 24 (0.00%) 0	4 / 26 (15.38%) 4
Tremors pre-infusion in hands/fingers subjects affected / exposed occurrences (all)	Additional description: Tremors pre-infusion in hands/fingers	
	1 / 24 (4.17%) 1	0 / 26 (0.00%) 0
Tingling in legs subjects affected / exposed occurrences (all)	Additional description: Tingling in legs	
	2 / 24 (8.33%) 2	0 / 26 (0.00%) 0
Eye disorders Blurred Vision subjects affected / exposed occurrences (all)	Additional description: Blurred Vision	
	0 / 24 (0.00%) 0	2 / 26 (7.69%) 2
	Additional description: Intermittent blurred vision	
	0 / 24 (0.00%) 0	1 / 26 (3.85%) 1
Right eye discolouration, left eye red, some soren	Additional description: Right eye discolouration, left eye red, some soren	

subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 26 (3.85%) 1	
Gastrointestinal disorders			
Nausea	Additional description: A little nausea		
subjects affected / exposed occurrences (all)	3 / 24 (12.50%) 4	8 / 26 (30.77%) 10	
Diarrhea	Additional description: Diarrhea		
subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	1 / 26 (3.85%) 1	
Dry Mouth	Additional description: Dry Mouth		
subjects affected / exposed occurrences (all)	3 / 24 (12.50%) 3	15 / 26 (57.69%) 18	
Intermittent nausea	Additional description: Intermittent nausea		
subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 26 (3.85%) 1	
Stomach pain	Additional description: Stomach pain		
subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 26 (0.00%) 0	
Midline hernia	Additional description: Midline hernia		
subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 26 (0.00%) 0	
mouth ulcers	Additional description: mouth ulcers		
subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 26 (0.00%) 0	
Tooth Ache	Additional description: Tooth Ache		
subjects affected / exposed occurrences (all)	1 / 24 (4.17%) 1	0 / 26 (0.00%) 0	
Vomiting	Additional description: Vomiting		
subjects affected / exposed occurrences (all)	3 / 24 (12.50%) 3	1 / 26 (3.85%) 1	
Skin and subcutaneous tissue disorders			
Boils on face and chest	Additional description: Boils on face and chest		
subjects affected / exposed occurrences (all)	0 / 24 (0.00%) 0	1 / 26 (3.85%) 1	
Acne	Additional description: Acne		

subjects affected / exposed	1 / 24 (4.17%)	0 / 26 (0.00%)	
occurrences (all)	1	0	
Dry Skin	Additional description: Dry Skin		
subjects affected / exposed	0 / 24 (0.00%)	1 / 26 (3.85%)	
occurrences (all)	0	1	
Hives	Additional description: Hives		
subjects affected / exposed	1 / 24 (4.17%)	0 / 26 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Bone pain	Additional description: Aches and pains in bones		
subjects affected / exposed	1 / 24 (4.17%)	0 / 26 (0.00%)	
occurrences (all)	1	0	
Oedema	Additional description: Complaint regarding legs, ankle swelling		
subjects affected / exposed	1 / 24 (4.17%)	0 / 26 (0.00%)	
occurrences (all)	1	0	
Hip pain	Additional description: Hip pain		
subjects affected / exposed	1 / 24 (4.17%)	0 / 26 (0.00%)	
occurrences (all)	1	0	
Muscle pain in neck	Additional description: Muscle pain in neck		
subjects affected / exposed	0 / 24 (0.00%)	1 / 26 (3.85%)	
occurrences (all)	0	1	
Infections and infestations			
Gingival abscess	Additional description: bottom gum abscess		
subjects affected / exposed	0 / 24 (0.00%)	1 / 26 (3.85%)	
occurrences (all)	0	1	
Chest infection (resp.tract infection - Upper)	Additional description: Chest infection (resp.tract infection - Upper)		
subjects affected / exposed	1 / 24 (4.17%)	1 / 26 (3.85%)	
occurrences (all)	1	1	
Thrush (vaginal)	Additional description: Thrush (vaginal)		
subjects affected / exposed	1 / 24 (4.17%)	0 / 26 (0.00%)	
occurrences (all)	1	0	
Worms	Additional description: Worms		
subjects affected / exposed	1 / 24 (4.17%)	0 / 26 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			

Diabetes type 2 diagnosed subjects affected / exposed occurrences (all)	Additional description: Diabetes type 2 diagnosed		
	1 / 24 (4.17%) 1	0 / 26 (0.00%) 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

None reported