



Clinical trial results:

An Open-Label Study to Evaluate the Long-Term Safety, Tolerability, and Efficacy of OV101 in Individuals with Angelman Syndrome (ELARA)

Summary

EudraCT number	2019-004478-24
Trial protocol	DE NL
Global end of trial date	30 June 2021

Results information

Result version number	v1 (current)
This version publication date	12 May 2022
First version publication date	12 May 2022

Trial information

Trial identification

Sponsor protocol code	OV101-18-002
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03882918
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Ovid Therapeutics Inc
Sponsor organisation address	1460 Broadway , New York, United States, 10036
Public contact	Todd F. Baumgartner, M.D., MPH, Ovid Therapeutics Inc., 1 8027525168, tbaumgartner@ovidrx.com
Scientific contact	Todd F. Baumgartner, M.D., MPH, Ovid Therapeutics Inc., 1 8027525168, tbaumgartner@ovidrx.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	13 September 2021
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 June 2021
Global end of trial reached?	Yes
Global end of trial date	30 June 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study is to evaluate the long-term safety and tolerability of OV101 in individuals with AS assessed by the incidence and severity of AEs and SAEs in study participants who are at least 2 years old at the time of enrollment into this study

Protection of trial subjects:

All study subjects were required to read and sign an Informed Consent Form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 January 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: 4
Country: Number of subjects enrolled	Germany: 6
Country: Number of subjects enrolled	Israel: 19
Country: Number of subjects enrolled	Australia: 9
Country: Number of subjects enrolled	United States: 103
Worldwide total number of subjects	141
EEA total number of subjects	10

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)	83
Adolescents (12-17 years)	17
Adults (18-64 years)	41

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants in the study completed OV101-15-001 or OV101-16-001 and/or was a sibling of a participant who completed OV101-15-001, OV101-16-001, or OV101-19-001.

Pre-assignment

Screening details:

Subjects with Angelman Syndrome who completed the pharmacokinetic Study OV101-16-001 (NCT03109756) will also be permitted to participate, provided they meet all entry criteria.

Period 1

Period 1 title	Baseline & Recruitment (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

Not blinded

Arms

Arm title	OV101
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Arm description:

gaboxadol

Arm type	Experimental
Investigational medicinal product name	gaboxadol
Investigational medicinal product code	OV101
Other name	
Pharmaceutical forms	Capsule, soft
Routes of administration	Oral use

Dosage and administration details:

OV101 was supplied in 5 mg, 2 mg, and/or 0.5 mg capsules. Capsules were swallowed or the contents could be sprinkled (1 capsule to ≤ 1 teaspoon) on a low-fat, semi-liquid food; if enacted, this approach must have been used throughout the study.

Number of subjects in period 1	OV101
Started	141
Completed	1
Not completed	140
Consent withdrawn by subject	5
Adverse event, non-fatal	13
Other	9
Study Terminated by Sponsor	98
Lack of efficacy	14
Protocol deviation	1

Baseline characteristics

Reporting groups

Reporting group title	OV101
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Reporting group description:

gaboxadol

Reporting group values	OV101	Total	
Number of subjects	141	141	
Age categorical			
(NIH/OMB), there are subjects that chose multiple categories.			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	83	83	
Adolescents (12-17 years)	17	17	
Adults (18-64 years)	41	41	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: years			
arithmetic mean	14		
standard deviation	± 9.30	-	
Gender categorical			
Sex			
Units: Subjects			
Female	57	57	
Male	84	84	

Subject analysis sets

Subject analysis set title	Treated patients
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Subject analysis set type	Per protocol
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Subject analysis set description:

gaboxadol

Reporting group values	Treated patients		
Number of subjects	141		
Age categorical			
(NIH/OMB), there are subjects that chose multiple categories.			
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)	83		
Adolescents (12-17 years)	17		
Adults (18-64 years)	41		
From 65-84 years	0		
85 years and over	0		
Age continuous			
Units: years			
arithmetic mean	7.8		
standard deviation	± 3.04		
Gender categorical			
Sex			
Units: Subjects			
Female	57		
Male	84		

End points

End points reporting groups

Reporting group title	OV101
Reporting group description: gaboxadol	
Subject analysis set title	Treated patients
Subject analysis set type	Per protocol
Subject analysis set description: gaboxadol	

Primary: Incidence of adverse events in active treatment group

End point title	Incidence of adverse events in active treatment group ^[1]
End point description: This study was prematurely terminated.	
End point type	Primary
End point timeframe: Participants were to participate in the study for up to 166 weeks	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: No Statistical Analyses was performed

End point values	OV101			
Subject group type	Reporting group			
Number of subjects analysed	141			
Units: patients				
Number of subjects analysed	141			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All AEs that occurred from the time written informed consent and/or assent were obtained to the End Of Study visit were recorded in the source documentation and reported in the CRF.

Adverse event reporting additional description:

AEs were classified as "treatment-emergent" (i.e., TEAEs or serious TEAEs) if they occurred following the administration of IMP. All events reported in this database are treatment-emergent.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	22
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Reporting groups

Reporting group title	OV101
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Reporting group description:

gaboxadol

Serious adverse events	OV101		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 141 (2.13%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Nervous system disorders			
Partial seizures			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Seizure cluster			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Status epilepticus			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

Non-serious adverse events	OV101		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	106 / 141 (75.18%)		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	11 / 141 (7.80%)		
occurrences (all)	11		
Fatigue			
subjects affected / exposed	6 / 141 (4.26%)		
occurrences (all)	6		
Gait disturbance			
subjects affected / exposed	3 / 141 (2.13%)		
occurrences (all)	3		
Crying			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Discomfort			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Influenza like illness			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Medical device site oedema			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Social circumstances			
Patient uncooperative			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Reproductive system and breast disorders			

Penis disorder subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Respiratory, thoracic and mediastinal disorders			
Nasal congestion subjects affected / exposed occurrences (all)	2 / 141 (1.42%) 2		
Rhinorrhoea subjects affected / exposed occurrences (all)	2 / 141 (1.42%) 2		
Atelectasis subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Cough subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Hypoxia subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Sleep apnoea syndrome subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Psychiatric disorders			
Agitation subjects affected / exposed occurrences (all)	8 / 141 (5.67%) 8		
Irritability subjects affected / exposed occurrences (all)	8 / 141 (5.67%) 8		
Middle insomnia subjects affected / exposed occurrences (all)	7 / 141 (4.96%) 7		
Sleep disorder subjects affected / exposed occurrences (all)	7 / 141 (4.96%) 7		
Aggression			

subjects affected / exposed	6 / 141 (4.26%)		
occurrences (all)	6		
Insomnia			
subjects affected / exposed	6 / 141 (4.26%)		
occurrences (all)	6		
Anxiety			
subjects affected / exposed	5 / 141 (3.55%)		
occurrences (all)	5		
Abnormal behaviour			
subjects affected / exposed	4 / 141 (2.84%)		
occurrences (all)	4		
Inappropriate affect			
subjects affected / exposed	3 / 141 (2.13%)		
occurrences (all)	3		
Dermatillomania			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Enuresis			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Initial insomnia			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Decreased interest			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Disruptive mood dysregulation disorder			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Intentional self-injury			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Nail picking			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		

Stubbornness			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Terminal insomnia			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Tic			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Investigations			
Weight decreased			
subjects affected / exposed	3 / 141 (2.13%)		
occurrences (all)	3		
Activated partial thromboplastin time prolonged			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Alanine aminotransferase increased			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Blood glucose decreased			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Blood thyroid stimulating hormone increased			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Amylase increased			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		

Blood creatine increased subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Blood insulin increased subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Blood potassium increased subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Blood uric acid increased subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Mean cell volume increased subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Menstruation normal subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Neutrophil count decreased subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Weight increased subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
White blood cell count increased subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Injury, poisoning and procedural complications			
Fall subjects affected / exposed occurrences (all)	5 / 141 (3.55%) 5		
Contusion subjects affected / exposed occurrences (all)	2 / 141 (1.42%) 2		
laceration			

subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Animal bite			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Ankle fracture			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Bite			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Concussion			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Foot fracture			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Head injury			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Joint injury			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Ligament rupture			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Skin abrasion			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Tooth fracture			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Congenital, familial and genetic disorders			
Developmental hip dysplasia			

subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Tachycardia			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Nervous system disorders			
Seizure			
subjects affected / exposed	10 / 141 (7.09%)		
occurrences (all)	10		
Somnolence			
subjects affected / exposed	8 / 141 (5.67%)		
occurrences (all)	8		
Generalised tonic-clonic seizure			
subjects affected / exposed	6 / 141 (4.26%)		
occurrences (all)	6		
Petit mal epilepsy			
subjects affected / exposed	6 / 141 (4.26%)		
occurrences (all)	6		
Tremor			
subjects affected / exposed	6 / 141 (4.26%)		
occurrences (all)	6		
Headache			
subjects affected / exposed	3 / 141 (2.13%)		
occurrences (all)	3		
Lethargy			
subjects affected / exposed	3 / 141 (2.13%)		
occurrences (all)	3		
Myoclonus			
subjects affected / exposed	3 / 141 (2.13%)		
occurrences (all)	3		
Partial seizures			

subjects affected / exposed	3 / 141 (2.13%)		
occurrences (all)	3		
Clonic convulsion			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Dyskinesia			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Seizure cluster			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Status epilepticus			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Action tremor			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Altered state of consciousness			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Atonic seizures			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Cognitive disorder			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Hypertonia			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Intention tremor			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Syncope			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Tardive dyskinesia			

subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Tonic convulsion			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Increased tendency to bruise			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Eye disorders			
Conjunctival haemorrhage			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Photophobia			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	13 / 141 (9.22%)		
occurrences (all)	13		
Constipation			
subjects affected / exposed	9 / 141 (6.38%)		
occurrences (all)	9		
Diarrhoea			
subjects affected / exposed	4 / 141 (2.84%)		
occurrences (all)	4		
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 141 (2.13%)		
occurrences (all)	3		
Nausea			

subjects affected / exposed	3 / 141 (2.13%)		
occurrences (all)	3		
Dental caries			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Retching			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Toothache			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Abdominal discomfort			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Anal incontinence			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Aphthous ulcer			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Eructation			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Gastric ulcer			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Gastritis			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Glossitis			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Haematemesis			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Hiatus hernia			

subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Ileus			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Incarcerated hiatus hernia			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Mallory-Weiss syndrome			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Tongue ulceration			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Tooth development disorder			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Tooth impacted			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	5 / 141 (3.55%)		
occurrences (all)	5		
Dermatitis allergic			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Dermatitis diaper			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Alopecia			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Decubitus ulcer			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		

Eczema subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Renal and urinary disorders Acute kidney injury subjects affected / exposed occurrences (all)	2 / 141 (1.42%) 2		
Urinary retention subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Musculoskeletal and connective tissue disorders Arthritis subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Joint swelling subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Muscular weakness subjects affected / exposed occurrences (all)	1 / 141 (0.71%) 1		
Infections and infestations Upper respiratory tract infection subjects affected / exposed occurrences (all)	14 / 141 (9.93%) 14		
Nasopharyngitis subjects affected / exposed occurrences (all)	11 / 141 (7.80%) 11		
corona virus infection subjects affected / exposed occurrences (all)	9 / 141 (6.38%) 9		
Urinary tract infection subjects affected / exposed occurrences (all)	6 / 141 (4.26%) 6		
Gastroenteritis subjects affected / exposed occurrences (all)	5 / 141 (3.55%) 5		

Pneumonia			
subjects affected / exposed	4 / 141 (2.84%)		
occurrences (all)	4		
Otitis media			
subjects affected / exposed	4 / 141 (2.84%)		
occurrences (all)	4		
Conjunctivitis			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Enterobiasis			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Fungal infection			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Gastroenteritis viral			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Influenza			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
lung infection			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Pharyngitis streptococcal			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Sinusitis			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Viral infection			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		
Tooth infection			
subjects affected / exposed	2 / 141 (1.42%)		
occurrences (all)	2		

Adenovirus infection			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Bronchitis			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Campylobacter gastroenteritis			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Cellulitis			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Device related infection			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Ear infection			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Gingivitis			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Helicobacter infection			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Laryngitis viral			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Leishmaniasis			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Oral herpes			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Oral infection			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		

Pharyngitis			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Respiratory tract infection viral			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Rhinovirus infection			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Urinary tract infection fungal			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	6 / 141 (4.26%)		
occurrences (all)	6		
Abnormal loss of weight			
subjects affected / exposed	5 / 141 (3.55%)		
occurrences (all)	5		
Dehydration			
subjects affected / exposed	3 / 141 (2.13%)		
occurrences (all)	3		
Hypercalcaemia			
subjects affected / exposed	1 / 141 (0.71%)		
occurrences (all)	1		

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

Online references

<http://www.ncbi.nlm.nih.gov/pubmed/33395098>