Clinical trial results:
A randomized, double-blind, placebo-controlled study to evaluate the safety and tolerability of OCS-05 in patients with acute optic neuritis

Summary

EudraCT number	2020-003147-29
Trial protocol	FR
Global end of trial date	16 September 2024

Results information

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

Trial information

Trial identification

Sponsor protocol code	OCS-05_P2_01

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Oculis
Sponsor organisation address	Avenue de la Gare 39, Lausanne, Switzerland,
Public contact	Oculis, Oculis, info@oculis.com
Scientific contact	Oculis, Oculis , info@oculis.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	15 July 2025
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 September 2024
Global end of trial reached?	Yes
Global end of trial date	16 September 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the safety and tolerability of OCS-05 in participants with optic neuritis.

Protection of trial subjects:

This study was conducted in accordance with International Council on Harmonisation (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 February 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 33
Worldwide total number of subjects	33
EEA total number of subjects	33

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)	33
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants who met all the inclusion and none of the exclusion criteria were enrolled in this study.

Pre-assignment

Screening details:

Informed consent, eligibility determination, blood sample, ophthalmology examinations, neurology examinations

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	OCS-05 3 mg/kg/day + Steroid

Arm description:

FAS (full analysis set) randomized and treated

Arm type	Experimental
Investigational medicinal product name	OCS-05 + IV methylprednisolone
Investigational medicinal product code	
Other name	Privosegtor
Pharmaceutical forms	Infusion
Routes of administration	Infusion

Dosage and administration details:

OCS-05 at 3 mg/kg/day for 5 days + IV methylprednisolone at 1g/day

Arm title	OCS-05 2 mg/kg/day + Steroid

Arm description:

FAS (full analysis set) randomized and treated

Arm type	Experimental
Investigational medicinal product name	OCS-05 + IV methylprednisolone
Investigational medicinal product code	
Other name	Privosegtor
Pharmaceutical forms	Infusion
Routes of administration	Infusion

Dosage and administration details:

OCS-05 2 mg/kg/day for 5 days + IV methylprednisolone at 1g/day

Arm title	Placebo + Steroid

Arm description:

FAS (full analysis set) randomized and treated

Arm type	Placebo
Investigational medicinal product name	Placebo + IV methylprednisolone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:
0.9% sodium chloride sterile saline solution (NaCl) + IV methylprednisolone at 1g/day

Number of subjects in period 1	OCS-05 3 mg/kg/day + Steroid	OCS-05 2 mg/kg/day + Steroid	Placebo + Steroid
Started	15	4	14
Completed	15	4	14

Baseline characteristics

Reporting groups	
Reporting group title	OCS-05 3 mg/kg/day + Steroid
Reporting group description:	
FAS (full analysis set) randomized and treated	
Reporting group title	OCS-05 2 mg/kg/day + Steroid
Reporting group description:	
FAS (full analysis set) randomized and treated	
Reporting group title	Placebo + Steroid
Reporting group description:	
FAS (full analysis set) randomized and treated	

Reporting group values	OCS-05 3 mg/kg/day + Steroid	OCS-05 2 mg/kg/day + Steroid	Placebo + Steroid
Number of subjects	15	4	14
Age categorical Units: Subjects			
<30	6	0	6
[30, 40]	5	1	5
>=40	4	3	3
Gender categorical Units: Subjects			
Female	9	4	10
Male	6	0	4

Reporting group values	Total		
Number of subjects	33		
Age categorical Units: Subjects			
<30	12		
[30, 40]	11		
>=40	10		
Gender categorical Units: Subjects			
Female	23		
Male	10		

End points

End points reporting groups

Reporting group title	OCS-05 3 mg/kg/day + Steroid
Reporting group description: FAS (full analysis set) randomized and treated	
Reporting group title	OCS-05 2 mg/kg/day + Steroid
Reporting group description: FAS (full analysis set) randomized and treated	
Reporting group title	Placebo + Steroid
Reporting group description: FAS (full analysis set) randomized and treated	

Primary: Percentage of subjects with shift from normal (baseline) to abnormal in any ECG parameter

End point title	Percentage of subjects with shift from normal (baseline) to abnormal in any ECG parameter
End point description: Percentage of subjects with shift from normal (baseline) to abnormal in any ECG parameter	
End point type	Primary
End point timeframe: Baseline (V3-t1 before IMP or V1) to V3-t1 after IMP to V4 (Primary endpoint)	

End point values	OCS-05 3 mg/kg/day + Steroid	OCS-05 2 mg/kg/day + Steroid	Placebo + Steroid	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	14	2	8	
Units: subjects				
Heart Rate	1	0	1	
PR Interval	0	0	0	
QRS duration	1	0	0	
QTcB Interval	0	0	0	
QTcF Interval	1	0	0	
Overall	2	0	1	

Statistical analyses

Statistical analysis title	Shift From Normal to Abnormal in Any ECG Parameter
Comparison groups	OCS-05 3 mg/kg/day + Steroid v OCS-05 2 mg/kg/day + Steroid v Placebo + Steroid

Number of subjects included in analysis	24
Analysis specification	Pre-specified
Analysis type	other[1]
Parameter estimate	Risk difference (RD)
Point estimate	1.8
Confidence interval	
level	90 %
sides	2-sided
lower limit	-31.2
upper limit	29.3

Notes:

[1] - Between group comparison based on risk differences with 90% exact confidence interval for the difference.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

The period of observation for collection of AEs extended from the time the subject gave informed consent until the last study visit.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.1

Reporting groups

Reporting group title	OCS-05 3 mg/kg/day + Steroid
Reporting group description: -	
Reporting group title	OCS-05 2 mg/kg/day + Steroid
Reporting group description: -	
Reporting group title	Placebo + Steroid

Reporting group description: -

Serious adverse events	OCS-05 3 mg/kg/day + Steroid	OCS-05 2 mg/kg/day + Steroid	Placebo + Steroid
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	1 / 14 (7.14%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Nervous system disorders			
MYELITIS			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
MULTIPLE SCLEROSIS RELAPSE			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	OCS-05 3 mg/kg/day + Steroid	OCS-05 2 mg/kg/day + Steroid	Placebo + Steroid
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 15 (80.00%)	4 / 4 (100.00%)	14 / 14 (100.00%)
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Phlebitis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Catheter site pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Discomfort			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Infusion site phlebitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Puncture site pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Gait disturbance			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal			

disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Anxiety			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Euphoric mood			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Mixed anxiety and depressive disorder			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Electrocardiogram QRS complex prolonged			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Biopsy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Blood alkaline phosphatase increased			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Electrocardiogram QT prolonged			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Transaminases increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Post lumbar puncture syndrome			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Procedural headache			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Procedural pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Road traffic accident			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			

Headache			
subjects affected / exposed	4 / 15 (26.67%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	4	0	1
Paraesthesia			
subjects affected / exposed	2 / 15 (13.33%)	1 / 4 (25.00%)	1 / 14 (7.14%)
occurrences (all)	2	1	1
Optic neuritis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	2 / 14 (14.29%)
occurrences (all)	1	0	3
Uhthoff's phenomenon			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Dizziness			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Dizziness postural			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Electric shock sensation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypoaesthesia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Motor dysfunction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Sensory disturbance			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Sensory loss			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Tremor			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	2 / 15 (13.33%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	2	0	1
Neutrophilia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 4 (25.00%)	1 / 14 (7.14%)
occurrences (all)	1	1	1
Hyperleukocytosis			
subjects affected / exposed	1 / 15 (6.67%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Anaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Iron deficiency anaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Monocytopenia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypochromic anaemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
DIPLOPIA			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Dry eye			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Ocular hyperaemia			

subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Retinal tear			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	4
Abdominal pain			
subjects affected / exposed	1 / 15 (6.67%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Constipation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Nausea			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Segmental diverticular colitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorder			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Hepatobiliary disorders			
HEPATIC CYTOLYSIS			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	2 / 15 (13.33%)	1 / 4 (25.00%)	1 / 14 (7.14%)
occurrences (all)	2	1	1
Rash pruritic			

subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	2
Dermatitis acneiform			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Papule			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Rosacea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Leukocyturia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Renal colic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 4 (25.00%)	1 / 14 (7.14%)
occurrences (all)	1	1	1
Myalgia			

subjects affected / exposed	1 / 15 (6.67%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	1	2	0
NECK PAIN			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 15 (0.00%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
COVID-19			
subjects affected / exposed	2 / 15 (13.33%)	1 / 4 (25.00%)	3 / 14 (21.43%)
occurrences (all)	2	1	3
Influenza			
subjects affected / exposed	2 / 15 (13.33%)	1 / 4 (25.00%)	0 / 14 (0.00%)
occurrences (all)	2	1	0
Pharyngitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Bronchitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Genital infection fungal			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Gingivitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Rash pustular			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Diabetic metabolic decompensation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 4 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 4 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	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

None reported