Clinical trial results:
A Phase 3 Randomised, Double-Masked, Placebo-Controlled Study of the Effect of OMS302 on Intraoperative Pupil Diameter in Subjects at High Risk of Intraoperative Floppy Iris Syndrome Undergoing Intraocular Lens Replacement

Summary

EudraCT number	2013-003885-15
Trial protocol	DE AT
Global end of trial date	11 August 2014

Results information

Result version number	v1 (current)
This version publication date	19 January 2019
First version publication date	19 January 2019

Trial information

Trial identification

Sponsor protocol code	OMS302-ILR-006

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02093689
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Omeros Corporation
Sponsor organisation address	201 Elliott Avenue West, Seattle, United States, 98119
Public contact	Clinical Operations Coordinator, Iris Pharma, 33 (0)493 594 959, info@iris-pharma.com
Scientific contact	Clinical Operations Coordinator, Iris Pharma, 33 (0)493 594 959, info@iris-pharma.com
Sponsor organisation name	Omeros Corporation
Sponsor organisation address	201 Elliott Ave W, Seattle, United States, 98119
Public contact	Andrea Kessler, Omeros Corporation, 011 12066765000, akessler@omeros.com
Scientific contact	Soyoung Han, Omeros Corporation, 011 12066765000, shan@omeros.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	No

1901/2006 apply to this trial?	

Notes:

Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	11 August 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	11 August 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of Part 1 of the study is to evaluate whether intraoperative pupil diameter can be accurately measured in subjects at high risk for Intraoperative Floppy Iris Syndrome (IFIS).

The primary objective of Part 2 of the study is to evaluate the effect of OMS302 compared to placebo when administered in irrigation solution during intraocular lens replacement in subjects at high risk for IFIS on:

- Intraoperative pupil diameter.

Protection of trial subjects:

None.

Background therapy:

None.

Evidence for comparator:

None.

Actual start date of recruitment	29 November 2013
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	Austria: 7
Country: Number of subjects enrolled	Germany: 7
Worldwide total number of subjects	14
EEA total number of subjects	14

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)	0
From 65 to 84 years	11
85 years and over	3

Subject disposition

Recruitment

Recruitment details:

Adult males 18 years or older.

Pre-assignment

Screening details:

None.

Pre-assignment period milestones

Number of subjects started	14
Number of subjects completed	14

Period 1

Period 1 title	Baseline Analysis Popluation
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	OMS302

Arm description:

OMS302 diluted in balanced salt solution (BSS) and administered as irrigation solution.

Arm type	Experimental
Investigational medicinal product name	OMS302
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for intraocular irrigation
Routes of administration	Intraocular use

Dosage and administration details:

4.4 mL added to BSS solution during cataract surgery.

Number of subjects in period 1	OMS302
Started	14
Completed	14

Period 2

Period 2 title	Overall Study
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	OMS302

Arm description:

OMS302 diluted in balanced salt solution (BSS) and administered as irrigation solution.

Arm type	Experimental
Investigational medicinal product name	OMS302
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for solution for intraocular irrigation
Routes of administration	Intraocular use

Dosage and administration details:

4.4 mL added to BSS solution during cataract surgery.

Number of subjects in period 2	OMS302
Started	14
Completed	14

Baseline characteristics

Reporting groups

Reporting group title	Baseline Analysis Popluation

Reporting group description: -

Reporting group values	Baseline Analysis Popluation	Total	
Number of subjects	14	14	
Age categorical Units: Subjects			
Adults >= 65 years	14	14	
Gender categorical Units: Subjects			
Female	0	0	
Male	14	14	

End points

End points reporting groups

Reporting group title	OMS302
Reporting group description:	
OMS302 diluted in balanced salt solution (BSS) and administered as irrigation solution.	
Reporting group title	OMS302
Reporting group description:	
OMS302 diluted in balanced salt solution (BSS) and administered as irrigation solution.	

Primary: Pupil diameter

End point title	Pupil diameter[1]
End point description:	
The primary objective of Part 1 of the study is to evaluate whether intraoperative pupil diameter can feasibly be measured in subjects at high risk for Intraoperative Floppy Iris Syndrome (IFIS).	
End point type	Primary
End point timeframe:	
After 15 patients enrolled.	

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: Pupil measurement methodology determined not to be appropriate in this population and data were not analyzed from any participant.

End point values	OMS302			
Subject group type	Reporting group			
Number of subjects analysed	0[2]			
Units: pixels				
number (not applicable)				

Notes:

[2] - Pupil measurement methodology determined not to be appropriate in this population.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: AE's are collected from time of consent through the last visit of follow-up.	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	14.1
Reporting groups	
Reporting group title	Part 1
Reporting group description: Part 1 will be an open-label study in which all subjects receive OMS302	

Serious adverse events	Part 1		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 14 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 0.05 %

Non-serious adverse events	Part 1		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 14 (21.43%)		
Investigations			
Intraocular pressure increased			
subjects affected / exposed	2 / 14 (14.29%)		
occurrences (all)	2		
Surgical and medical procedures			
Zonulolysis			
subjects affected / exposed	1 / 14 (7.14%)		
occurrences (all)	1		
Eye disorders			
Iridocele			
subjects affected / exposed	1 / 14 (7.14%)		
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? Yes

Date	Interruption	Restart date
11 August 2014	Pupil measurement methodology determined not to be appropriate in this population.	-

Notes:

Limitations and caveats

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

Pupil measurement methodology determined not to be appropriate in this population.

Notes: