Clinical trial results:
The effect of intravenous glucocorticoids on the tearfilm in eyes with thyroid-associated ophthalmopathy

Summary

EudraCT number	2012-001910-40
Trial protocol	AT
Global end of trial date	17 July 2018

Results information

Result version number	v1 (current)
This version publication date	26 January 2020
First version publication date	26 January 2020

Trial information

Trial identification

Sponsor protocol code	OPHT-120312

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University of Vienna
Sponsor organisation address	Währinger Gürtel 18-20, Vienna, Austria,
Public contact	Univ. Klinik f. Klin. Pharmakologie, Medizinische Universität Wien, +43 1404002981, klin-pharmakologie@meduniwien.ac.at
Scientific contact	Univ. Klinik f. Klin. Pharmakologie, Medizinische Universität Wien, +43 1404002981, klin-pharmakologie@meduniwien.ac.at

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	17 August 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 July 2018
Global end of trial reached?	Yes
Global end of trial date	17 July 2018
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the change in tear film thickness in eyes with thyroid-associated ophthalmopathy treated with intravenous glucocorticoids

Protection of trial subjects:

Subjects were during the trial continuously under the supervision of a physician or an experienced nurse.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 July 2012
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: 18
Worldwide total number of subjects	18
EEA total number of subjects	18

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)	18
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were recruited by use of the data base of the Clinical Pharmacology, Medical University of Vienna.

Pre-assignment

Screening details:

check of the In- and Exclusion criteria, physical examination, vital signs, laboratory assessment

Period 1

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

Arms

Arm title	One group

Arm description:

A total of 24 patients will enter the trial. Only patients already scheduled for treatment with systemic glucocorticoids (according to the kahaly-scheme) will be included in the study.

Arm type	Experimental
Investigational medicinal product name	Methylprednisolone (Urbason, Sanofi-Aventis)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

500mg methylprednisolone iv once weekly for 6 weeks, followed by 250mg methylprednisolone iv once weekly for 6 weeks

Number of subjects in period 1	One group
Started	18
Completed	6
Not completed	12
technical difficulties	12

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	18	18	
Age categorical 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)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	18	18	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	12	12	
Male	6	6	

End points

End points reporting groups

Reporting group title	One group

Reporting group description:

A total of 24 patients will enter the trial. Only patients already scheduled for treatment with systemic glucocorticoids (according to the kahaly-scheme) will be included in the study.

Primary: Tear film thickness measured with high resolution OCT

End point title	Tear film thickness measured with high resolution OCT[1]

End point description:

End point type	Primary

End point timeframe:

Evaluation after 6 and 12 weeks treatment

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: on account of early termination no statistical analysis have been made

End point values	One group			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: µm	6			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 27.06.2013-17.07.2018	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.1

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

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Medication was well tolerated.

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
17 July 2018	Cooperation Partner was no longer working at the Medical university of Vienna	-

Notes:

Limitations and caveats

None reported