



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