



Clinical trial results:

Longterm efficiency and safety of intravitreal injections with bevacizumab in patients with neovascularisation or macular edema.

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2013-005056-15 |
| Trial protocol | BE |
| Global end of trial date | 09 July 2024 |

Results information

| | |
|-----------------------------------|--|
| Result version number | v1 (current) |
| This version publication date | 02 May 2025 |
| First version publication date | 02 May 2025 |
| Summary attachment (see zip file) | Final Study Report (2013-005056-15_Avastin_FinalStudyReport.pdf) |

Trial information

Trial identification

| | |
|-----------------------|--------------|
| Sponsor protocol code | AGO/2013/012 |
|-----------------------|--------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | University Hospital Ghent |
| Sponsor organisation address | C. Heymanslaan, Ghent, Belgium, 9000 |
| Public contact | HIRUZ, UZ Gent, 0032 93320530, hiruz.ctu@uzgent.be |
| Scientific contact | HIRUZ, UZ Gent, 0032 93320530, hiruz.ctu@uzgent.be |

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 April 2025 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 09 July 2024 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

evaluate the long-term safety and efficacy of intravitreal treatment with bevacizumab by registration of best corrected visual acuity, side-effects and central retinal thickness as measured with the ocular coherence tomography if available

Protection of trial subjects:

See attachment

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 24 February 2014 |
| 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 | Belgium: 583 |
| Worldwide total number of subjects | 583 |
| EEA total number of subjects | 583 |

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) | 583 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

See attachment

Pre-assignment

Screening details:

See attachment

Period 1

| | |
|----------------|-------------------------|
| Period 1 title | Global (overall period) |
|----------------|-------------------------|

| | |
|------------------------------|-----|
| Is this the baseline period? | Yes |
|------------------------------|-----|

| | |
|-------------------|----------------|
| Allocation method | Not applicable |
|-------------------|----------------|

| | |
|---------------|-------------|
| Blinding used | Not blinded |
|---------------|-------------|

Blinding implementation details:

See attachment

Arms

| | |
|-----------|--------|
| Arm title | Global |
|-----------|--------|

Arm description:

See attachment

| | |
|----------|-------------------|
| Arm type | Active comparator |
|----------|-------------------|

| | |
|--|-------------|
| Investigational medicinal product name | Bevacizumab |
|--|-------------|

| | |
|--|--|
| Investigational medicinal product code | |
|--|--|

| | |
|------------|--|
| Other name | |
|------------|--|

| | |
|----------------------|---------------------------------|
| Pharmaceutical forms | Solution for injection/infusion |
|----------------------|---------------------------------|

| | |
|--------------------------|------------------------|
| Routes of administration | Solution for injection |
|--------------------------|------------------------|

Dosage and administration details:

See attachment

| Number of subjects in period 1 | Global |
|--------------------------------|--------|
| Started | 583 |
| Completed | 583 |

Baseline characteristics

End points

End points reporting groups

| | |
|------------------------------|--------|
| Reporting group title | Global |
| Reporting group description: | |
| See attachment | |

Primary: Endpoint

| | |
|------------------------|-------------------------|
| End point title | Endpoint ^[1] |
| End point description: | |
| See attachment | |
| End point type | Primary |
| End point timeframe: | |
| See attachment | |

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: See attachment

| | | | | |
|-----------------------------|-----------------|--|--|--|
| End point values | Global | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 583 | | | |
| Units: See attachment | | | | |
| number (not applicable) | 583 | | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

See attachment

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|--------------------|--------|
| Dictionary name | MedDRA |
| Dictionary version | 0 |

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: See attachment

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