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