



Clinical trial results:

Intravitreal ranibizumab in patients with retinal pigment epithelial detachments secondary to AMD

Summary

EudraCT number	2008-004675-22
Trial protocol	DE
Global end of trial date	22 December 2014

Results information

Result version number	v1 (current)
This version publication date	11 January 2022
First version publication date	11 January 2022
Summary attachment (see zip file)	Manuscript - Monthly IVL in PED (Manuscript - Monthly IVL in vPED.pdf)

Trial information

Trial identification

Sponsor protocol code	ADM-PED08
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00976222
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Universitätsklinikum Bonn
Sponsor organisation address	Sigmund-Freud-Str. 25, Bonn, Germany, 53105
Public contact	Klinisches Studienzentrum, Universitätsklinikum Münster, Klinik für Augenheilkunde, 49 2518356048, augenklinik-studien@ukmuenster.de
Scientific contact	Klinisches Studienzentrum, Universitätsklinikum Münster, Klinik für Augenheilkunde, 49 2518356048, augenklinik-studien@ukmuenster.de

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	31 May 2016
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	22 December 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- to demonstrate the efficacy of ranibizumab in patients with retinal pigment epithelial detachment secondary to AMD

Protection of trial subjects:

The study medication has already been authorized for the treatment of age related macula degeneration. The investigator informed the patient about the study in detail and both undersigned the informed consent form. A patient insurance was in place. Adverse events were documented regularly. As needed and at the discretion of the ophthalmologist all patients could also be treated with Verteporfin within the scope of photodynamic therapy.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 December 2008
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	Germany: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

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)	5
From 65 to 84 years	33
85 years and over	2

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Informed consent has to be signed and Inclusion/Exclusion criteria must match. The study medication can be administered at baseline visit in consideration of the clinical investigation as well as imaging processes.

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	Ranibizumab
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Arm description:

Every study patient was treated with Ranibizumab 0,5

Arm type	single arm
Investigational medicinal product name	Ranibizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Intraocular instillation solution
Routes of administration	Intravitreal use

Dosage and administration details:

Patients were treated monthly with intravitreal 0.5 mg ranibizumab injections

Number of subjects in period 1	Ranibizumab
Started	40
Completed	40

Baseline characteristics

Reporting groups

Reporting group title	Overall trial
Reporting group description: -	

Reporting group values	Overall trial	Total	
Number of subjects	40	40	
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)	5	5	
From 65-84 years	33	33	
85 years and over	2	2	
Gender categorical			
Units: Subjects			
Female	23	23	
Male	17	17	

Subject analysis sets

Subject analysis set title	Full analysis set
Subject analysis set type	Full analysis
Subject analysis set description:	
All patients who were enrolled	

Reporting group values	Full analysis set		
Number of subjects	40		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	5		
From 65-84 years	33		
85 years and over	2		

Gender categorical			
Units: Subjects			
Female	23		
Male	17		

End points

End points reporting groups

Reporting group title	Ranibizumab
Reporting group description: Every study patient was treated with Ranibizumab 0,5	
Subject analysis set title	Full analysis set
Subject analysis set type	Full analysis
Subject analysis set description: All patients who were enrolled	

Primary: Mean BCVA

End point title	Mean BCVA ^[1]
End point description:	

End point type	Primary
End point timeframe: Baseline - Month 12	

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	Ranibizumab			
Subject group type	Reporting group			
Number of subjects analysed	40			
Units: whole	40			

Attachments (see zip file)	Manuscript - Monthly IVL in PED/Manuscript - Monthly IVL in
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Statistical analyses

No statistical analyses for this end point

Primary: Decrease in PED height

End point title	Decrease in PED height ^[2]
End point description:	

End point type	Primary
End point timeframe: Baseline - Month12	

Notes:

[2] - 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	Ranibizumab			
Subject group type	Reporting group			
Number of subjects analysed	40			
Units: whole	40			

Attachments (see zip file)	Manuscript - Monthly IVL in vPED/Manuscript - Monthly IVL in
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Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From baseline to completion visit (4 weeks after last administration of study medication)

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	16.0
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Reporting groups

Reporting group title	Bonn/Münster
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Reporting group description:

All patients receiving at least one time study medication

Reporting group title	Munich
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Reporting group description:

All patients receiving at least one time study medication

Serious adverse events	Bonn/Münster	Munich	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 20 (5.00%)	2 / 20 (10.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
Cerebral microangiopathy			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Basaliom	Additional description: Non-study eye		
subjects affected / exposed	0 / 20 (0.00%)	2 / 20 (10.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hospitalisation	Additional description: Hospitalisation due to radioiodine therapy for thyroid hyperfunction		
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	Bonn/Münster	Munich	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 20 (15.00%)	3 / 20 (15.00%)	
Blood and lymphatic system disorders			
Increased blood pressure			
subjects affected / exposed	1 / 20 (5.00%)	3 / 20 (15.00%)	
occurrences (all)	1	1	
foot edema			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Immune system disorders			
Pollen allergy			
subjects affected / exposed	0 / 20 (0.00%)	1 / 20 (5.00%)	
occurrences (all)	0	1	
Eye disorders			
hyposphagma			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 20 (5.00%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Infections and infestations			
Common cold			
subjects affected / exposed	1 / 20 (5.00%)	2 / 20 (10.00%)	
occurrences (all)	1	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? No

Limitations and caveats

None reported