Clinical trial results:
Switching to aflibercept in patients with neovascular AMD not responding to anti-VEGF treatment.

Summary

EudraCT number	2013-001208-12
Trial protocol	NL
Global end of trial date	01 May 2015

Results information

Result version number	v1 (current)
This version publication date	26 July 2021
First version publication date	26 July 2021
Summary attachment (see zip file)	Manuscript (vanAsten switching to aflibercept.pdf)

Trial information

Trial identification

Sponsor protocol code	44122

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Radboudumc
Sponsor organisation address	Philips van leydenlaan 15, Nijmegem, Netherlands,
Public contact	Investigator, Radboud University Nijmegen Medical Centre, f.vanasten@ohk.umcn.nl
Scientific contact	Investigator, Radboud University Nijmegen Medical Centre, f.vanasten@ohk.umcn.nl

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	01 May 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 May 2015
Global end of trial reached?	Yes
Global end of trial date	01 May 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this study is to examine features of treatment response on optical coherence tomography in patients with neovascular age-related macular degeneration who switched to aflibercept after non-response to previous intravitreal anti-VEGF treatment.

Protection of trial subjects:

In accordance to section 10, subsection 1, of the WMO, the investigator will inform the subjects and the reviewing accredited METC if anything occurs, on the basis of which it appears that the disadvantages of participation may be significantly greater than was foreseen in the research proposal. The study will be suspended pending further review by the accredited METC, except insofar as suspension would jeopardise the subjects' health. The investigator will take care that all subjects are kept informed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 2013
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	Netherlands: 9
Worldwide total number of subjects	9
EEA total number of subjects	9

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)	2
From 65 to 84 years	5

85 years and over	2

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

patients with neovascular age-related macular degeneration that have shown inadequate response to anti-VEGF treatment, defined as a persistant central retinal thickness on optical coherence tomography (OCT) of ≥300 µm

Period 1

Period 1 title	Baseline
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	aflibercept

Arm description: -

Arm type	Experimental
Investigational medicinal product name	aflibercept
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravitreal use

Dosage and administration details:

2 mg in 0.05 mL

Number of subjects in period 1	aflibercept
Started	9
Completed	9

Period 2

Period 2 title	3 months
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	aflibercept
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	aflibercept
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for solution for injection
Routes of administration	Intravitreal use

Dosage and administration details:

2 mg in 0.05 mL

Number of subjects in period 2	aflibercept
Started	9
Completed	9

Baseline characteristics

Reporting groups	
Reporting group title	Baseline

Reporting group description: -

Reporting group values	Baseline	Total	
Number of subjects	9	9	
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)	2	2	
From 65-84 years	5	5	
85 years and over	2	2	
Age continuous			
75 (55-87)			
Units: years			
median	75		
full range (min-max)	55 to 87	-	
Gender categorical			
male 4 female 5			
Units: Subjects			
Female	5	5	
Male	4	4	

End points

End points reporting groups

Reporting group title	aflibercept
Reporting group description: -	
Reporting group title	aflibercept
Reporting group description: -	

Primary: central retinal thickness

End point title	central retinal thickness
End point description:	
End point type	Primary
End point timeframe:	
3 months	

End point values	aflibercept	aflibercept		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	9		
Units: micrometer(s)				
number (not applicable)	9	9		

Statistical analyses

Statistical analysis title	change in CRT

Statistical analysis description:

The change in central retinal thickness between inclusion and one month after 3 monthly aflibercept injections will be measured on OCT imaging in µm and will be presented as the mean change in central retinal thickness from baseline (± standard deviation). In case of missing data, the patient cannot be included in the analysis. Whether change in central retinal thickness is significant will be determined by paired T-test.

Comparison groups	aflibercept v aflibercept
Number of subjects included in analysis	18
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	< 0.05
Method	t-test, 2-sided
Parameter estimate	Median difference (final values)

Notes:

[1] - paired T-test

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: SAE: 15 days SAE life threatening: 7 days	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

Frequency threshold for reporting non-serious adverse events: 1 %

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: there were no adverse events reported in this study.

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

Online references

http://www.ncbi.nlm.nih.gov/pubmed/27350361