EU Clinical Trials Register

Clinical trial results:
fMRI analysis of the visual cortex in neovascular Age-related Macular Degeneration

Summary

EudraCT number	2013-004769-15
Trial protocol	AT
Global end of trial date	17 December 2018

Results information

Result version number	v1 (current)
This version publication date	23 May 2020
First version publication date	23 May 2020

Trial information

Trial identification

Sponsor protocol code	V1.2

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, Wien, Austria, 1090
Public contact	Vienna Study Center, Universitätsklinik für Augenheilkunde, Medizinische Universität Wien, 0043 1404004847, renate.baltas@meduniwien.ac.at
Scientific contact	Vienna Study Center, Universitätsklinik für Augenheilkunde, Medizinische Universität Wien, 4040048471 1404004847, renate.baltas@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 December 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	17 December 2018
Global end of trial reached?	Yes
Global end of trial date	17 December 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the activation pattern of the primary visual cortex in nAMD patients before and after ranibizumab therapy and to compare it with healthy controls.

Protection of trial subjects:

Ranibizumab intravitreal injections were administered according to the label. Patient safety standards of the Dept. of Ophthalmology of the Medical University of Vienna were applied.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 December 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	Austria: 41
Worldwide total number of subjects	41
EEA total number of subjects	41

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	37
85 years and over	2

Subject disposition

Recruitment

Recruitment details: -	

Pre-assignment

Screening details:

Twenty eyes of 20 patients with treatment-naïve nAMD were recruited for this study

Pre-assignment period milestones

Number of subjects started	41
Number of subjects completed	41

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Treatment group

Arm description:

Patients with treatment naive neovascular age-related macular degeneration were treated with 3 monthly intravitreal injections of Ranibizumab.

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

Dosage and administration details:

0,05 mL (=0,5mg) Ranibizumab

Arm title	Control group

Arm description:

Healthy age-matched controls

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Treatment group	Control group
Started	20	21
Completed	20	21

Baseline characteristics

Reporting groups

Reporting group title	Overall trial (overall period)

Reporting group description: -

Reporting group values	Overall trial (overall period)	Total	
Number of subjects	41	41	
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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Units: years			
arithmetic mean	75.3		
standard deviation	± 6.88	-	
Gender categorical			
Units: Subjects			
Female	27	27	
Male	14	14	

End points

End points reporting groups

Reporting group title	Treatment group
Reporting group description:	
Patients with treatment naive neovascular age-related macular degeneration were treated with 3 monthly intravitreal injections of Ranibizumab.	
Reporting group title	Control group
Reporting group description:	
Healthy age-matched controls	

Primary: Functional magnetic resonance imaging

End point title	Functional magnetic resonance imaging[1]
End point description:	
End point type	Primary
End point timeframe:	
Baseline vs Month 3	

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: In order to visualise the difference of active voxels numbers when comparing baseline and month 3 runs, data of all subjects were combined and visualised through a histogram in visual field space. The inner 9.4° visual angle were separated into nine concentric annuli and a central disk. The relative change of suprathreshold pRF centre voxel numbers inside these annuli were then compared for baseline and post-ranibizumab loading dose runs over all patients.

End point values	Treatment group	Control group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	20	21		
Units: Active V1 voxels				
number (not applicable)	20	21		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:	
During treatment phase for each patient.	
Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17

Reporting groups

Reporting group title	Patients
Reporting group description: -	

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: No non-serious adverse event was recorded

Serious adverse events	Patients		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 20 (15.00%)		
number of deaths (all causes)	3		
number of deaths resulting from adverse events			
Gastrointestinal disorders			
Gastritis			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	1 / 1		
Hepatobiliary disorders			
Liver disorder			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	1 / 1		
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 20 (5.00%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	1 / 1		

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

Non-serious adverse events	Patients		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 20 (0.00%)		

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