Clinical trial results:
Intravitreal Lucentis (Ranibizumab) in acute central serous Chrioretinopathy
- a prospective, randomized, single blind monocentric study

Summary

EudraCT number	2010-020902-13
Trial protocol	AT
Global end of trial date	04 September 2014

Results information

Result version number	v1 (current)
This version publication date	02 January 2021
First version publication date	02 January 2021

Trial information

Trial identification

Sponsor protocol code	0001-2010

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University Innsbruck
Sponsor organisation address	Christoph-Probst-Platz 1, Innrain 52 A, Innsbruck, Austria, 6020
Public contact	RCS Studie, Chefsekretariat, Universitätsklinik für Augenheilkunde und Optometrie, Medizinische Universität Innsbruck, +43 51250423720, bernhard.steger@i-med.ac.at
Scientific contact	RCS Studie, Chefsekretariat, Universitätsklinik für Augenheilkunde und Optometrie, Medizinische Universität Innsbruck, +43 51250423720, bernhard.steger@i-med.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	04 September 2014
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 September 2014
Global end of trial reached?	Yes
Global end of trial date	04 September 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To test the safety and efficacy of intravitreal injections with Lucentis (Ranibizumab) in acute onset CSC. Primary outcome measure is the resolution of neurosensory detachment as measured by optic coherence tomography six months after study inclusion.

Protection of trial subjects:

N/A

Background therapy:

-

Evidence for comparator:

-

Actual start date of recruitment	01 July 2011
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: 99999
Worldwide total number of subjects	99999
EEA total number of subjects	99999

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)	99999
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No patients were recruited for this trial. "99999" is a value for 0 participants.

Pre-assignment

Screening details:

N/A

Period 1

Period 1 title	Treatment period (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

N/A

Arms

Arm title	Lucentis/ Placebo

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Lucentis
Investigational medicinal product code	
Other name	Ranibizumab
Pharmaceutical forms	Injection
Routes of administration	Intravitreal use

Dosage and administration details:

Subjects would have received intravitreal injection of 0.5mg (0.05mL) Lucentis under sterile conditions up to three times during the whole trial.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Other use

Dosage and administration details:

Subjects would have received a "sham-injection" of 0.05mL placebo under sterile conditions up to three times during the whole trial.

Number of subjects in period 1	Lucentis/ Placebo
Started	99999
Completed	99999

Baseline characteristics

Reporting groups

Reporting group title	Treatment period

Reporting group description: -

Reporting group values	Treatment period	Total	
Number of subjects	99999	99999	
Age categorical			
No patients were enrolled in this trial. "99999" is a value for 0 participants.			
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)	99999	99999	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
No patients were enrolled in this trial. "99999" is a value for 0 participants.			
Units: years			
arithmetic mean	0		
standard deviation	± 0	-	
Gender categorical			
No patients were enrolled in this trial. "99999" is a value for 0 participants.			
Units: Subjects			
Female	99999	99999	
Male	0	0	

End points

End points reporting groups

Reporting group title	Lucentis/ Placebo

Reporting group description: -

Primary: Neurosensory detachment

End point title	Neurosensory detachment[1]

End point description:

Primary outcome measure is the resolution of neurosensory detachment as measured by optic coherence tomography six months after study inclusion.

End point type	Primary

End point timeframe:

6 months

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: No subjects were enrolled in this trial, therefore no statistical analysis was done.

End point values	Lucentis/ Placebo			
Subject group type	Reporting group			
Number of subjects analysed	99999[2]			
Units: µm				
number (not applicable)	99999			

Notes:

[2] - No subjects were recruited for this trial. " 99999" is a value for 0 participants.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

01.07.2011- 04.09.2014

Adverse event reporting additional description:

No patients were included in this trial, therefore no AEs or SAEs were reported.

Assessment type	Systematic

Dictionary used

Dictionary name	CTCAE
Dictionary version	4.03

Reporting groups

Reporting group title	Lucentis/ Placebo

Reporting group description: -

Serious adverse events	Lucentis/ Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

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

Non-serious adverse events	Lucentis/ Placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 99999 (0.00%)		

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 subjects were enrolled in this trial, therefore no AEs or SAEs were observed.

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

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No subjects were enrolled in this trial. "99999" is a value for 0 participants , as it was not possible to fill in "0" for the number of included patients.

Notes: