Clinical trial results: *Full title of Trial**

Summary

EudraCT number*	2014-000986-30
Trial protocol	
Global end of trial date*	July 10th 2018

Trial information

Trial identification

Sponsor protocol code*	140109

Additional study identifiers

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

Notes:

Sponsors details*

Sponsor organisation name	IRCCS Ospedale San Raffaele
Sponsor organisation address	Via Olgettina, 60, Milano, Italy, 20132
Public contact	
Scientific contact	

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

Results analysis stage

Analysis stage*	Final
Date of interim/final analysis*	
Is this the analysis of the primary completion data?*	Yes
Global end of trial reached?*	Yes
Global end of trial date*	
Was the trial ended prematurely?	No

General information about the trial

Main objective of the trial*: *Enter a description for the mail objective(s) of the trial*

Actual start date of recruitment*	1srt November 2015
Long term follow-up planned*	No
If Yes, rationale:	n/a
Duration	Months – Years N/A
Independent data monitoring committee (IDMC) involvement?*	No
Protection of trial subjects*:	no
Background therapy:	
Evidence for comparator:	

Population of trial subjects

Subjects enrolled per country

Country:	
Planned number of subjects	
Actual Number of subjects enrolled*	23 eyes of 20 patients
Worldwide total number of subjects	
EEA total number of subjects	

Subjects enrolled per age group

In utero*	0
Preterm newborn - gestational age < 37wks*	0
Newborns (0-27 days)*	0
Infants and toddlers (28 days-23months)*	0
Children (2-11 years)*	0
Adolescents (12-17 years)*	0
Adults (18-64 years)*	5
From 65 to 84 years*	15
85 years and over*	1

Subject disposition

Recruitment details: *Enter key information relevant to the recruitment process for the trial (eg gates of recruitment period and territories)*

Pre-assignment - *Screening details*: *Enter relevant information related to screening (eg screening criteria, significant events and approaches)*

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

Arms	
Arm title*	*Treatment*
Arm description:	
Arm type*	Experimental
Investigational medicinal product name*	**Eylea 2mg**
Investigational medicinal product code	
Other name	
Pharmaceutical forms*	Eylea® 40 mg/ml solution for injection
Routes of administration*	**Intravitreal**
Dosage and administration details*	40 mg/mL

Number of subjects in period	Arm Title (overall population)	Arm Title *(repeat for each arms if applicable)*
Started*	23	
Completed*	20	
Subject non-completion reason (if applicable)		
AE, non fatal		
AE, fatal		
Consent withdrawn by subject		
Lack of efficacy		
Lost to follow up	3	
Physician decision		
Pregnancy		
Protocol Deviation		
Other		

Baseline characteristics

Reporting groups* Overall cohort	
Reporting group title*	Overall cohort
Number of subjects at the baseline*	23

Reporting group description: *You can report per arm in the baseline period or for the overall baseline period*

Subject analysis sets

Add a subject analysis set if you wish to report on groups different from the reporting group defined above (repeat if applicable)

Subject analysis set title*	Overall cohort
Subject analysis set type*	Full Analysis
Subject analysis set description*	consecutively enrolled patients with active CNV secondary to AS and followed for 18 months
Number of subjects in subjects analysis set*	*20*

Age characteristics*

Complete either the age categorical, age continuous or complete both these characteristics in order to collect values for the reporting groups and optionally the subject analysis sets.

	Characteristic title*	Units*	Age categories*
Age categorical			

	Characteristic title*	Units*	Central tendency*	Dispersion type*
Age continuous	Overall cohort 59.57 (13.28)	Years	Arithmetic Mean	standard deviation

Gender characteristics*

	Characteristic title*	Units*	Gender categories*
Gender categorical	8	people	Female

Study specific characteristics

	Characteristic title*	Units*	Categories*	Number of subject for each categories
Study specific categorical	Race	people	Caucasian	19
Study specific categorical	Lens status	eyes	Pseudophakia	9
Study specific categorical	Foveal involvement	eyes	Foveal involvement	23
Study specific categorical				
Study specific categorical				

End points

Add subject analysis set if you wish to report on groups different form reporting groups defined above

Subject analysis set title*	Overall cohort
Subject analysis set type*	Full Analysis
Subject analysis set description*	consecutively enrolled patients with active CNV secondary to AS and followed for 18 months
Number of subject in subject analysis set *	20

End points definitions

End point title*	best-corrected visual acuity	
		Values
Countable or measurable?*	measurable	-
If countable, Countable units*:		
If measurable, Measurable units*	LogMAR	
Measure type*:	Arithmetic Mean	
Precision/dyspersion type*	Standard deviation	

End point type*	Primary

End point timeframe*:
18 months

Use categories only if the data for the end point can be categorized

Category title

Specify the groups of subjects applicable to this end point

Reporting groups*			
Period	18 months		
Arms	treatment		
subject analysis sets	20 subjects		

Adverse events

Adverse events information

Timeframe for reporting adverse events*: *18 months*

First patient first visit: November 20th 2015
Last recruitment date: January 3rd 2017
Study closure: July 10th 2018

Adverse event reporting additional description: *Enter information about the AE collection and provide details about the method of assessment and monitoring*

All adverse events (AEs) will be prospectively collected from the time of the first study-related procedure through the end of the follow-up period (18 months post-enrollment). AEs will be assessed during each scheduled visit and through additional patient self-reporting, when applicable. Events will be recorded using a standardized case report form. The assessment includes both patient-reported symptoms and investigator-assessed findings based on clinical examination and ancillary testing.

Assessment type*	Systematic
Frequency threshold for reporting non-serious adverse events*	≥0% in any study arm or reporting group

Dictionary used

Dictionary name*	MedDRA or CTCAE
Dictionary version*	25.1

Adverse events reporting group definition

Use arms from baseline period as reporting groups
OR

Reporting group title*: *Overall cohort*

For this reporting group, provide the following totals:

Subject exposed*	20
Subjects affected by non -SAE*	13
Total number of deaths (all causes)*	0
Total number of deaths resulting from adverse event*	0

Serious adverse event details and values

Serious Adverse Event 1

System Organ Class: Eye disorders
Event term: Endophthalmitis
Related to study treatment: Possibly related

Serious Adverse Event 2

System Organ Class: Gastrointestinal disorders
Event term: Acute gastritis
Related to study treatment: Not related

Values for serious adverse event per reporting group *

Reporting groups	Subjects affected number	Subjects exposed number	Occurrences all number	Occurrences causally related to treatment number	Fatalities number	Fatalities causally related to treatment number
	2	20	2	1	0	0

Non - Serious adverse event details and values

System organ class*:

Event term*:

Values for non-serious adverse event per reporting group*

Threshold for non-serious adverse event reporting is:

Reporting groups	Subjects affected number	Subjects exposed number	Occurrences all number
Overall cohort			

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol*? No

Date	Amendment

Notes:

Interruptions (globally)

Were there any global interruptions to the trial*? No

If Yes, Interruption date

Interruption description

Limitations and caveats

None reported

Online references

Parodi MB, Cicinelli MV, Marchese A, Giuffrè C, Viola F, Staurenghi G, Varano M, Bandello F. Intravitreal aflibercept for management of choroidal neovascularization secondary to angioid streaks : The Italian EYLEA-STRIE study. Eur J Ophthalmol. 2021 May;31(3):1146-1153. doi: 10.1177/1120672120928305. Epub 2020 Jun 2. PMID: 32483995.S