Clinical trial results:
Pilot study on robot assisted retinal vein cannulation with ocriplasmin infusion for central retinal vein occlusion.

Summary

EudraCT number	2015-005473-20
Trial protocol	BE
Global end of trial date	13 April 2017

Results information

Result version number	v1 (current)
This version publication date	25 November 2020
First version publication date	25 November 2020
Summary attachment (see zip file)	Publication Acta Ophthalmologica (ACTA-19-09-1176.R1_Proof_hi.pdf)

Trial information

Trial identification

Sponsor protocol code	V121102015

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	UZ Leuven Gasthuisberg
Sponsor organisation address	Herestraat 49, Leuven, Belgium, 3020
Public contact	Peter Stalmans, UZ Leuven, 32 16341819, peter.stalmans@uzleuven.be
Scientific contact	Peter Stalmans, UZ Leuven, 32 16341819, peter.stalmans@uzleuven.be

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	13 April 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 April 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study aims at investigating the therapeutic effect of local intravenous administration of ocriplasmin in patients with a central retinal vein occlusion. The primary outcome measure is change in visual acuity after 6 months

Protection of trial subjects:

following standard pre-/per- and post-operative patient care (time-out procedures, sterility checks, postoperative assessments, etc.) safety is monitored and assessed during every foreseen contact with the patient.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 February 2016
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	Belgium: 4
Worldwide total number of subjects	4
EEA total number of subjects	4

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	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

patients with recent diagnosis of CRVO

Pre-assignment

Screening details:

recent diagnosis of CRVO

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	first arm
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	ocriplasmin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 500 µg	
Arm title	second arm
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	first arm	second arm
Started	4	1
Completed	4	1

Baseline characteristics

Reporting groups	
Reporting group title	overall trial

Reporting group description: -

Reporting group values	overall trial	Total	
Number of subjects	4	4	
Age categorical			
between 18 - 80 yrs			
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)	4	4	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	1	1	
Male	3	3	

End points

End points reporting groups

Reporting group title	first arm
Reporting group description: -	
Reporting group title	second arm
Reporting group description: -	

Primary: change in visual acuity

End point title	change in visual acuity
End point description:	
End point type	Primary
End point timeframe:	
First analysis: 1 month after treatment of the last enrolled patient Final analysis: 6 months after the last treatment of the last enrolled patient	

End point values	first arm	second arm		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	1[1]		
Units: LogMar				
number (not applicable)	4	1		

Notes:

[1] - control group

Attachments (see zip file)	acta-10-09/ACTA-19-09-1176.R1_Proof_hi.pdf

Statistical analyses

Statistical analysis title	Robot assisted surgery
Statistical analysis description:	
Statistical analysis was done using SPSS 24.0.	
Comparison groups	first arm v second arm
Number of subjects included in analysis	5
Analysis specification	Pre-specified
Analysis type	other[2]
P-value	< 0.05
Method	Wilcoxon (Mann-Whitney)
Parameter estimate	mean Standard Deviation

Notes:

[2] - Because of the small amount of data non-parametric related samples, Wilcoxon signed rank tests were used to analyze changes in continuous data. Statistical significance was considered when the two-sided p-value is below 0.05. Values are depicted as mean ±Standard Deviation (SD).

Adverse events

Adverse events information	
Timeframe for reporting adverse events: 3 calendar days following the date of awareness by the investigational site study personel	
Assessment type	Systematic

Dictionary used	
Dictionary name	MEDDEV
Dictionary version	7

Reporting groups	
Reporting group title	single open

Reporting group description: -

Serious adverse events	single open		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	single open		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)		
Eye disorders			
high eye pressure			
subjects affected / exposed	2 / 4 (50.00%)		
occurrences (all)	4		
rubeosis iridis			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	4		

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