Clinical trial results:
Early treatment of patients with central serous retinopathy: A randomized controlled trial

Summary

EudraCT number	2009-017959-98
Trial protocol	NL
Global end of trial date	04 July 2018

Results information

Result version number	v1
This version publication date	23 August 2018
First version publication date	23 August 2018

Trial information

Trial identification

Sponsor protocol code	OZR-2009-26

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Nederlands Trial Register: NTR2261

Notes:

Sponsors

Sponsor organisation name	Rotterdam Eye Hospital
Sponsor organisation address	PO Box 70030, Rotterdam, Netherlands, 3000LM
Public contact	Rotterdam Ophthalmic Institute, The Rotterdam Eye Hospital, 31 (0)104023449, roi@oogziekenhuis.nl
Scientific contact	Rotterdam Ophthalmic Institut, Rotterdam Ophthalmic Institute The Rotterdam Eye Hospital, 31 (0)104023449, roi@oogziekenhuis.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	30 July 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 July 2018
Global end of trial reached?	Yes
Global end of trial date	04 July 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the outcome in CSR patients comparing treatment with PDT versus observation.

Protection of trial subjects:

No specific measures.

Background therapy:

There is no agreement concerning the early treatment of central serous retinopathy (CSR). In literature, clinical case series using photodynamic therapy (PDT) show favorable results. In this study patients were randomized between an observational and an early PDT treatment arm. In the observational arm, patients with persistent lesions at 3 months were treated with PDT in agreement with current standard of care.

Evidence for comparator: -

Actual start date of recruitment	24 August 2010
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 52
Worldwide total number of subjects	52
EEA total number of subjects	52

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)	52
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients presenting with CSR with poor prognostic factors.

Pre-assignment

Screening details:

No previous history of CSR in either eye.
Poor prognostic acute CSR with at least one of the following lesion characteristics: 1) initial localization within 1 disk diameter of the fovea, 2) number of lesions 3 or more, 3) total lesion surface 1 disk area or more.

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?	Yes
Arm title	Control

Arm description:

No immediate treatment

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Active

Arm description:

Immediate PDT.

Arm type	Experimental
Investigational medicinal product name	Photodynamic therapy (Visudyne)
Investigational medicinal product code	Visudyne
Other name	verteporfine
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Body weight corrected dose, single administration

Number of subjects in period 1	Control	Active
Started	26	26
Completed	21	22
Not completed	5	4
Lost to follow-up	5	4

Baseline characteristics

Reporting groups	
Reporting group title	Control
Reporting group description:	
No immediate treatment	
Reporting group title	Active
Reporting group description:	
Immediate PDT.	

Reporting group values	Control	Active	Total
Number of subjects	26	26	52
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	44.5	43.1	
standard deviation	± 7.6	± 7.1	-
Gender categorical			
Units: Subjects			
Female	9	4	13
Male	17	22	39
Visual acuity			
BCVA on ETDRS			
Units: letters			
arithmetic mean	82.0	84.5	
standard deviation	± 10.8	± 5.0	-
Central foveal thickness			
Units: micrometers			
arithmetic mean	400	428	
standard deviation	± 124	± 117	-

End points

End points reporting groups	
Reporting group title	Control
Reporting group description: No immediate treatment	
Reporting group title	Active
Reporting group description: Immediate PDT.	

Primary: Visual acuity at 12 months	
End point title	Visual acuity at 12 months
End point description:	
End point type	Primary
End point timeframe: Visual acuity at 12 months	

End point values	Control	Active		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	22	21		
Units: letters				
arithmetic mean (standard deviation)	89.2 (± 7.5)	90.5 (± 5.7)		

Statistical analyses

Statistical analysis title	Comparison
Statistical analysis description: Independent t-test	
Comparison groups	Control v Active
Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	t-test, 2-sided
Parameter estimate	Mean difference (final values)
Variability estimate	Standard deviation

Secondary: Visual acuity change at 3 months	
End point title	Visual acuity change at 3 months

End point description:

End point type	Secondary

End point timeframe:

Visual acuity change from baseline to 3 months

End point values	Control	Active		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	24		
Units: letters				
arithmetic mean (standard deviation)	3.2 (± 6.3)	4.5 (± 5.9)		

Statistical analyses

No statistical analyses for this end point

Secondary: Central foveal thickness change at 3 months

End point title	Central foveal thickness change at 3 months

End point description:

End point type	Secondary

End point timeframe:

Central foveal thickness change from baseline to 3 months

End point values	Control	Active		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	25	24		
Units: micrometers				
arithmetic mean (standard deviation)	-133 (± 113)	-186 (± 127)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: 12 months	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21

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

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: Photodynamic therapy was performed by injecting the standard body weight corrected dosage of Visudyne® followed by activation of the lesion after 5 minutes with a non-thermic diode laser. No non-serious adverse events were obserbed.

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