Clinical trial results:
Influence of sustained-release dexamethasone on intraocular cytokines and growth factors and retinal blood vessels in retinal vein occlusion

Summary

EudraCT number	2012-000800-13
Trial protocol	AT
Global end of trial date	01 October 2014

Results information

Result version number	v1 (current)
This version publication date	12 March 2020
First version publication date	12 March 2020

Trial information

Trial identification

Sponsor protocol code	V1

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medizinische Universität Wien
Sponsor organisation address	Währinger Gürtel 18-20, Wien, Austria, 1090
Public contact	MUW, Universitätsklinik für Augenheilkunde und Optometrie, Medizinische Universität Wien, +43 1404007931, stefan.sacu@meduniwien.ac.at
Scientific contact	MUW, Universitätsklinik für Augenheilkunde und Optometrie, Medizinische Universität Wien, +43 1404007931, stefan.sacu@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	04 September 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	01 October 2014
Global end of trial reached?	Yes
Global end of trial date	01 October 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To investigate the effect of intravitreal Ozurdex® treatment on the anterior chamber cytokine and growth factor levels and on retinal vessel oxygenation after either CRVO or BRVO

Protection of trial subjects:

A recent study demonstrated the safety of intravitreal Ozurdex® treatment over a 12 month period. Most of the examination techniques used in this study are non-invasive. The only invasive investigation is anterior chamber paracentesis, but this is usually well tolerated and its safety has been demonstrated in previous studies. The risk/benefit ratio is therefore acceptable.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	31 January 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: 40
Worldwide total number of subjects	40
EEA total number of subjects	40

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)	8
From 65 to 84 years	25
85 years and over	7

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

40 patients were recruited for this study; 25 with BRVO, and 15 with CRVO.

Period 1

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

Arms

Arm title	All patients

Arm description: -

Arm type	Intervention
Investigational medicinal product name	Dexamethasone intravitreal implant
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Implant in pre-filled syringe
Routes of administration	Intravitreal use

Dosage and administration details:

0,7mg

Number of subjects in period 1	All patients
Started	40
Completed	40

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial

Reporting group description: -

Reporting group values	Overall trial	Total	
Number of subjects	40	40	
Age categorical 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)	8	8	
From 65-84 years	25	25	
85 years and over	7	7	
Age continuous Units: years			
arithmetic mean	69.5		
standard deviation	± 10.6	-	
Gender categorical Units: Subjects			
Female	15	15	
Male	25	25	

End points

End points reporting groups

Reporting group title	All patients

Reporting group description: -

Primary: Cytokine levels

End point title	Cytokine levels[1]

End point description:

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: Justification: Anova and the paired t-test was performed to investigate the longitudinal changes in cytokine levels, retinal vessel diameters, retrobulbar flow velocities and retinal blood flow. A p-value ≤0.05 is considered as statistical significant. Descriptive analysis will be performed for patient´s demographic data, furthermore, chi²-Test was used for nominal parameters.

End point values	All patients			
Subject group type	Reporting group			
Number of subjects analysed	40			
Units: pg/ml				
arithmetic mean (standard deviation)	19.3 (± 8.2)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events, serious adverse events were collected by spontaneous reporting during the study period.
Nonserious adverse events and SUSARs are documented on an "Adverse event" page in the case record form.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17

Reporting groups

Reporting group title	Intraocular pressure increase

Reporting group description: -

Serious adverse events	Intraocular pressure increase		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 40 (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	Intraocular pressure increase		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 40 (30.00%)		
Eye disorders			
intraocular pressure increase			
subjects affected / exposed	12 / 40 (30.00%)		
occurrences (all)	12		

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