Clinical trial results:
Ozurdex in proliferative vitreoretinopathy; a randomised control trial

Summary

EudraCT number	2011-004498-96
Trial protocol	GB
Global end of trial date	31 December 2015

Results information

Result version number	v1 (current)
This version publication date	03 October 2020
First version publication date	03 October 2020
Summary attachment (see zip file)	End of study report (BEAVRS 2015 Abstract.pdf)

Trial information

Trial identification

Sponsor protocol code	CHAD1030

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Moorfields Eye Hospital NHS Foundation Trust
Sponsor organisation address	City Road, London, United Kingdom, EC1V 2PD
Public contact	Ms Nicola Harris Moorfields Eye Hospital NHS Foundation Trust, Moorfields Eye Hospital NHS Foundation Trust, 0044 2072533411, nicola.harris@moorfields.nhs.uk
Scientific contact	Mr David Charteris Moorfields Eye Hospital NHS Foundation Trust, Moorfields Eye Hospital NHS Foundation Trust, 0044 2072533411, david.charteris@moorfields.nhs.uk

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	08 December 2015
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 December 2015
Global end of trial reached?	Yes
Global end of trial date	31 December 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Does the use of an additional anti inflammatory agent (ozurdex) given at the time of surgery in patients with established PVR (scar tissue on the retina)result in an improved surgical outcome at 6 months after the surgery?

Protection of trial subjects:

Nil specific

Background therapy:

Standard post-operative regime with topical dexamethasone qid and topical chaloamphenicaol qid

Evidence for comparator:

Complete primary success in 51% of subjects in previous RCT at study centre
Charteris DG, Aylward GW, Wong D, Groenewald C, Asaria RHY, Bunce C
A randomised controlled trial of combined 5-fluorouracil and low molecular weight heparin in management of established proliferative vitreoretinopathy
Ophthalmology. 2004 111:2240-5

Actual start date of recruitment	31 October 2011
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	United Kingdom: 140
Worldwide total number of subjects	140
EEA total number of subjects	140

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)	115
From 65 to 84 years	25
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Recruitment went as planned at the study centre - 140 subjects

Pre-assignment

Screening details:

192 subjects were screed for eligibility. Of these 29 did not meet the inclusion criteria, 20 were eligible but not enrolled and 3 were enrolled but not randomised (silicone oil not used in surgery)

Pre-assignment period milestones

Number of subjects started	140
Number of subjects completed	140

Period 1

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

Blinding implementation details:

The operating surgeon was not blinded as the treatment (steroid implant) is obvious at the time of surgery The subject and trial are blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Treatment

Arm description:

0.7-mg slow-release dexamethasone implant given at completion of surgery and at oil removal (approximately 3 months later) Standard per-operative (subconjunctival betamethasone and cefuroxime) and post operative (tapering topical dexamethasone and chloramphenicol) given

Arm type	Experimental
Investigational medicinal product name	Slow release dexamenthasone implant
Investigational medicinal product code	
Other name	Ozurdex
Pharmaceutical forms	Implant
Routes of administration	Intraocular use

Dosage and administration details:

0.7mg given into the vitreous cavity with silicone oil

Arm title	Control

Arm description:

Standard per operative and post operative medications given (sub conjunctival betamethasone and cefuroxime and tapering post-operative dexamethasone and chloramphenicol)

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 1	Treatment	Control
Started	70	70
Completed	69	69
Not completed	1	1
Lost to follow-up	1	1

Baseline characteristics

Reporting groups	
Reporting group title	Treatment
Reporting group description:	
0.7-mg slow-release dexamethasone implant given at completion of surgery and at oil removal (approximately 3 months later) Standard per-operative (subconjunctival betamethasone and cefuroxime) and post operative (tapering topical dexamethasone and chloramphenicol) given	
Reporting group title	Control
Reporting group description:	
Standard per operative and post operative medications given (sub conjunctival betamethasone and cefuroxime and tapering post-operative dexamethasone and chloramphenicol)	

Reporting group values	Treatment	Control	Total
Number of subjects	70	70	140
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	60.6	61.6	
standard deviation	± 14.3	± 13.9	-
Gender categorical			
By patient group			
Units: Subjects			
Female	24	30	54
Male	46	40	86
ETDRS visual acuity			
Units: Subjects			
ETDRS VA	70	70	140
PVR grade			
Grade of PVR			
Units: clock hours,			
median	3	4	
inter-quartile range (Q1-Q3)	2 to 4	2 to 6	-

End points

End points reporting groups

Reporting group title	Treatment
Reporting group description:	
0.7-mg slow-release dexamethasone implant given at completion of surgery and at oil removal (approximately 3 months later) Standard per-operative (subconjunctival betamethasone and cefuroxime) and post operative (tapering topical dexamethasone and chloramphenicol) given	
Reporting group title	Control
Reporting group description:	
Standard per operative and post operative medications given (sub conjunctival betamethasone and cefuroxime and tapering post-operative dexamethasone and chloramphenicol)	

Primary: primary, stable retinal reattachment

End point title	primary, stable retinal reattachment
End point description:	
assessed clinically	
End point type	Primary
End point timeframe:	
6 months after recruitment	

End point values	Treatment	Control		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	69	69		
Units: subjects	49	46		

Statistical analyses

Statistical analysis title	primary outcome
Comparison groups	Control v Treatment
Number of subjects included in analysis	138
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.05
Method	Chi-squared
Parameter estimate	Odds ratio (OR)
Confidence interval	
level	95 %
sides	2-sided

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From recruitment start February 2012 to final follow up - February 2015

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	2004

Reporting groups

Reporting group title	treatment
Reporting group description: -	
Reporting group title	control
Reporting group description: -	

Serious adverse events	treatment	control	
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 70 (10.00%)	6 / 69 (8.70%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Eye disorders			
suture related abscess	Additional description: non-IMP related infection, all other SAEs were suystemic , non-fatal and not related to the IMP		
subjects affected / exposed[1]	7 / 7 (100.00%)	6 / 6 (100.00%)	
occurrences causally related to treatment / all	0 / 7	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.
Justification: The numbers are equal

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	treatment	control	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	66 / 70 (94.29%)	63 / 69 (91.30%)	
Eye disorders			
raised intraocular pressure	Additional description: Most common AE was raised IOP -		
subjects affected / exposed[2]	66 / 66 (100.00%)	63 / 63 (100.00%)	
occurrences (all)	66	63	

Notes:

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects

exposed for the reporting group. These numbers are expected to be equal.
Justification: The numbers are equal

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.

Retrospective

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/28237428