



Clinical trial results: Continuation of platelet inhibiting drugs in eyelid surgery. A randomized, double-masked, placebo-controlled clinical trial.

Summary

EudraCT number	2009-009986-32
Trial protocol	NL
Global end of trial date	20 January 2011

Results information

Result version number	v1 (current)
This version publication date	01 February 2016
First version publication date	04 December 2014

Trial information

Trial identification

Sponsor protocol code	OZR-2008-12
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-
Other trial identifiers	Nederlands Trial Register: NTR1932

Notes:

Sponsors

Sponsor organisation name	The Rotterdam Eye Hospital
Sponsor organisation address	PO Box 70030, Rotterdam, Netherlands, 3000-LM
Public contact	Rotterdam Ophthalmic Institute, The Rotterdam Eye Hospital, +31 10 4023449, roi@oogziekenhuis.nl
Scientific contact	Rotterdam Ophthalmic Institute, The Rotterdam Eye Hospital, +31 10 4023449, 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	20 January 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	20 January 2011
Global end of trial reached?	Yes
Global end of trial date	20 January 2011
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To demonstrate non-inferiority of continuation of platelet inhibiting drugs in eyelid surgery regarding the risk of haemorrhagic complications.

Protection of trial subjects:

In case of retrobulbar bleeding, the wound will be reopened to allow drainage of blood and/or cauterizing. If considered necessary, a lateral canthotomy will be performed. Visual acuity will be measured and the fundus will be viewed (in mydriasis).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 October 2009
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: 7
Worldwide total number of subjects	7
EEA total number of subjects	7

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)	1
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients using platelet inhibiting drugs (acetylsalicylic acid, carbasalate calcium), who are scheduled for surgical correction of involutional ectropion, entropion, or upper eyelid dermatochalasis without fat prolapse at The Rotterdam Eye Hospital.

Pre-assignment

Screening details:

Replacement of regular medication will start 7 days preop and will end at 3 days postop.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Active

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Acetylsalicylic acid
Investigational medicinal product code	RVG16466
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

As prescribed for individual patient.

Arm title	Placebo
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Arm description: -

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

As prescribed for individual patient.

Number of subjects in period 1	Active	Placebo
Started	4	3
Completed	4	3

Baseline characteristics

Reporting groups

Reporting group title	Active
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Reporting group values	Active	Placebo	Total
Number of subjects	4	3	7
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	68	69	
standard deviation	± 10	± 4	-
Gender categorical Units: Subjects			
Female	0	1	1
Male	4	2	6

End points

End points reporting groups

Reporting group title	Active
Reporting group description: -	
Reporting group title	Placebo
Reporting group description: -	

Primary: Peroperative bleeding

End point title	Peroperative bleeding
End point description:	
End point type	Primary
End point timeframe:	
peroperative	

End point values	Active	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	4	3		
Units: bleeding events	1	0		

Statistical analyses

Statistical analysis title	No statistics performed.
Comparison groups	Active v Placebo
Number of subjects included in analysis	7
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	< 0.05
Method	t-test, 1-sided

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Seven days preop until six weeks postop.

Adverse event reporting additional description:

No serious adverse events occurred. No postoperative bleeding occurred.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	10
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Reporting groups

Reporting group title	Placebo group.
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Reporting group description: -

Reporting group title	Active group.
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Reporting group description: -

Serious adverse events	Placebo group.	Active group.	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Placebo group.	Active group.	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	

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: Peroperative bleeding is primary outcome; excessive bleeding occurred once (active group).

Postoperative bleeding did not occur.

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? Yes

Date	Interruption	Restart date
20 January 2011	Shortly after the start of this study, it was decided that the Ocuoplastic Surgery Department of The Rotterdam Eye Hospital would be adopting the international guidelines with respect to the use of platelet inhibiting drugs in periods of surgical intervention. As an interruption of platelet inhibiting drugs for oculoplastic surgery was no longer recommended, this study was prematurely terminated.	-

Notes:

Limitations and caveats

None reported