Clinical trial results:
Does Hyaluronidase permit volume reduction in sub-Tenon anaestehesia?

Summary

EudraCT number	2005-001203-19
Trial protocol	GB
Global end of trial date	23 February 2006

Results information

Result version number	v1 (current)
This version publication date	09 September 2022
First version publication date	09 September 2022

Trial information

Trial identification

Sponsor protocol code	AN 05/6922

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Leeds Teaching Hosptials NHS Trust
Sponsor organisation address	Beckett Street, Leeds, United Kingdom, LS9 7TF
Public contact	LTHT R&I Manager, Leeds Teaching Hospitals NHS Trust Beckett Street Leeds LS9 7TF, 0113 2433144, daniel.skinner@nhs.net
Scientific contact	LTHT R&I Manager, Leeds Teaching Hospitals NHS Trust Beckett Street Leeds LS9 7TF, 0113 2433144, daniel.skinner@nhs.net

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	23 February 2006
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 February 2006
Global end of trial reached?	Yes
Global end of trial date	23 February 2006
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess and quantify if Hyaluronidase permits volume reduction of the local anaesthetic solution used for sub-Tenon's anaesthesia during cataract surgery.

Sub-Tenon's local anaesthesia is a well recognized technique in ophthalmic surgery. By injecting local anaesthetic solution in the sub-Tenon's space the eye is numbed and prevented from moving during surgery. Large volumes of solution can cause chemosis which can complicate the surgical field.This can be avoided by reducing the volume of the injection, which then reduces the quality of the block. Addition of Hyaluronidase increases the spread of the block, but can cause allergic reactions. It is not clear whether the ideal block can be achieved by simply increasing the volume of local anaesthetic, which may worsen the surgical field, or adding hyaluronidase and taking the additional, if small, risk of an adverse event.

Protection of trial subjects:

It is not the drug or the procedure that is being tested. Both the drugs and the procedure being used are part of standard protocols throughout the UK. What we are testing is the volume of drug that is needed to numb your eye without causing too many side effects and whether the addition of hyaluronidase permits a reduction in the volume.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 July 2005
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	United Kingdom: 66
Worldwide total number of subjects	66
EEA total number of subjects	0

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	66
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:
patients awaiting cataract surgery identified at SJUH and asked if they would like to join study

Period 1

Period 1 title	Trial Treatment (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Arm title	treatment arm

Arm description: -

Arm type	Experimental
Investigational medicinal product name	hyaluronidase
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection/infusion
Routes of administration	Injection

Dosage and administration details:
15 IU ml−1

Number of subjects in period 1	treatment arm
Started	66
Completed	66

Baseline characteristics

End points

End points reporting groups

Reporting group title	treatment arm

Reporting group description: -

Primary: verbal response scale from 0 (no pain) to 10 (worst imaginable pain).

End point title	verbal response scale from 0 (no pain) to 10 (worst imaginable pain).[1]

End point description:

End point type	Primary

End point timeframe:

at time of injection

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: trial was terminated early and no significant statistical analysis was performed

End point values	treatment arm			
Subject group type	Reporting group			
Number of subjects analysed	66[2]			
Units: verbal response scale				
number (not applicable)	66			

Notes:

[2] - VRS pain score of 0-4

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: reported to sponsor within 24 hours	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	1

Reporting groups	
Reporting group title	treatment arm

Reporting group description: -

Serious adverse events	treatment arm		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 66 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

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

Non-serious adverse events	treatment arm		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 66 (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: trial was terminated early and no serious adverse event reports have been made available.

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