Clinical trial results:
The effect of hypertonic saline on blood electrolytes, acid-base balance and hormones that regulate blood pressure

Summary

EudraCT number	2013-004466-34
Trial protocol	FI
Global end of trial date	23 May 2017

Results information

Result version number	v1 (current)
This version publication date	24 January 2025
First version publication date	24 January 2025

Trial information

Trial identification

Sponsor protocol code	005,1

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Helsinki University Central Hospital
Sponsor organisation address	Haartmaninkatu 4 C, Helsinki, Finland, 00290
Public contact	Department of Ophthalmology, Helsinki University Central Hospital, +358 947173161, pia.inborr@outlook.com
Scientific contact	Department of Ophthalmology, Helsinki University Central Hospital, +358 947173161, pia.inborr@outlook.com

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	Interim
Date of interim/final analysis	23 May 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 May 2017
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To study the safety of intravenous hypertonic saline in reducing intraocular pressure

Protection of trial subjects:

We required the patients to be fluent in Finnish or Swedish. We excluded patients diagnosed with heart and kidney failure, dementia, or another condition that markedly decreased their physical performance. We measured blood pressure and heart rate automatically with an anaesthesia monitor. We took measurements before the bolus (baseline), 10, 20, 60 and 120 minutes after the bolus. We asked the patients to grade the pain at the infusion site on a scale from 0 to 10; zero for no pain, and 10 for the most intense (intolerable) pain. Any other side effect was additionally recorded.

Background therapy:

We cannulated an antecubital vein in either the right or left arm. We rinsed the cannula with 3 ml physiologic saline to confirm its intravenous position. The IVTHS dose corresponds to a 20 ml injection for an 80 kg patient. We infused the bolus at 1 ml/s, and then rinsed the cannula and vein with physiologic saline using 5 ml after the bolus.

Evidence for comparator: -

Actual start date of recruitment	25 February 2014
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	Finland: 1
Worldwide total number of subjects	1
EEA total number of subjects	1

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	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Eligible to our study were patients who were 25–80 years old. We required the patients to be fluent in Finnish or Swedish. We excluded patients diagnosed with heart and kidney failure, dementia, or another condition that markedly decreased their physical performance.

Pre-assignment

Screening details:

We screened three patients for the study. One patient was excluded because we could not get any blood from the cannulated vein. One patient was excluded because of high blood pressure and severe obesity.

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	Overall study

Arm description:

All patients who received hypertonic NaCl intravenously.

Arm type	Experimental
Investigational medicinal product name	Natriumklorid Braun 234 mg/ml
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

We cannulated an antecubital vein in either the right or left arm. We rinsed the cannula with 3 ml physiologic saline to confirm its intravenous position. The dosage of IVHTS was 1 mmol/kg sodium chloride in all patients. We infused the bolus at 1 ml/s, and then rinsed the cannula and vein with physiologic saline using 5 ml after the bolus. We took blood samples from the same cannula.

Number of subjects in period 1	Overall study
Started	1
10 minutes	1
20 minutes	1
60 minutes	1
120 minutes	1
Completed	1

Baseline characteristics

Reporting groups	
Reporting group title	Overall trial
Reporting group description:	
All patients	

Reporting group values	Overall trial	Total	
Number of subjects	1	1	
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)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Adults	1	1	
Gender categorical			
Eligible to our study were men and women who were 25–80 years old.			
Units: Subjects			
Female	1	1	
Male	0	0	

Subject analysis sets	
Subject analysis set title	Laboratory values
Subject analysis set type	Full analysis
Subject analysis set description:	
The study ended prematurely. We only studied one patient. We had problems with the blood sample collection from the patients.	

Reporting group values	Laboratory values		
Number of subjects	1		
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		
Adults	1		
Gender categorical			
Eligible to our study were men and women who were 25–80 years old.			
Units: Subjects			
Female	1		
Male	0		

End points

End points reporting groups

Reporting group title	Overall study

Reporting group description:

All patients who received hypertonic NaCl intravenously.

Subject analysis set title	Laboratory values
Subject analysis set type	Full analysis

Subject analysis set description:

The study ended prematurely. We only studied one patient. We had problems with the blood sample collection from the patients.

Primary: Laboratory values 120 minutes after the bolus

End point title	Laboratory values 120 minutes after the bolus[1]

End point description:

We took blood samples from the patiens before the NaCl-bolus (baseline) and 10, 20, 60 ja 120 minutes after the bolus. We studied the following values: Na, K, Cl, Ca, albumin, phosphate, renin, aldosterone, serum osmolality, copeptin and blood gas analysis from the venous blood (pH, PCO2, base excess).

End point type	Primary

End point timeframe:

Laboratory values 120 minutes after bolus.

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: No results to be analysed.

End point values	Laboratory values			
Subject group type	Subject analysis set			
Number of subjects analysed	1			
Units: 1	1			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information
Timeframe for reporting adverse events:
120 minutes after the hypertonic saline bolus.
Adverse event reporting additional description:
We asked the patients to grade the pain at the infusion site on a scale from 0 to 10; zero for no pain, and 10 for the most intense (intolerable) pain. Any other side effect was additionally recorded.

Assessment type	Non-systematic

Dictionary used	
Dictionary name	VAS
Dictionary version	1

Reporting groups	
Reporting group title	Whole study
Reporting group description:	
All patients.	

Serious adverse events	Whole study		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (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	Whole study		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)		
Vascular disorders			
Headache	Additional description: Occipital pain. VAS 3.		
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Pain in the arm	Additional description: Pain in the infusion arm for 2.5 minutes time. VAS 3.		
subjects affected / exposed	1 / 1 (100.00%)		
occurrences (all)	1		

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
23 May 2017	We had problems taking blood samples from the cannula in the vein. We could only get the baseline samples and 10 minutes samples (one patient).	-

Notes:

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

We managed to study only one patient partially.

Notes: