



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 patients before the NaCl-bolus (baseline) and 10, 20, 60 and 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, PCO ₂ , 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

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|-----------------|-----|
| Dictionary name | VAS |
|-----------------|-----|

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|--------------------|---|
| 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.

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|---|
| We managed to study only one patient partially. |
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Notes: