# Clinical trial results:
# The Effects of Isovolumetric and Isoeffective Infusions of Colloid Versus Crystalloid on Renal Blood Flow and Cardiac Output

## Summary

| | |
|---|---|
| EudraCT number | 2013-003260-32 |
| Trial protocol | GB |
| Global end of trial date | 12 November 2015 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 14 April 2019 |
| First version publication date | 14 April 2019 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | 13090 |

**Additional study identifiers**

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

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | University of Nottingham |
| Sponsor organisation address | Jubilee Campus, Triumph Road, Nottingham, United Kingdom, NG8 1DH |
| Public contact | Shone, University of Nottingham, +44 1159315679, dileep.lobo@nottingham.ac.uk |
| Scientific contact | Angela Shone, Professor Dileep Lobo, +44 115 8467906, sponsor@nottingham.ac.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 | 12 November 2015 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 12 November 2015 |
| Global end of trial reached? | Yes |
| Global end of trial date | 12 November 2015 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of this study is to determine the differential impact of isovolumetric and isoeffective infusions of crystalloid and gelatin on blood volume expansion - to test whether an infusion of a gelatin based colloid solution expands blood volume to a greater degree than an isovolumetric infusion of crystalloid, resulting in increased renal blood flow and perfusion, and cardiac output..

Protection of trial subjects:

All interventions carried out on healthy volunteers in the presence of qualified doctors

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 02 September 2013 |
| 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: 12 |
| Worldwide total number of subjects | 12 |
| EEA total number of subjects | 12 |

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) | 12 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

Recruitment period 02.10.2014 to 12.11.2015

### Pre-assignment

Screening details:

12 healthy, male volunteers, aged between 18 and 40 and weight between 65 and 80 kg. 2 participants later withdrew and were excluded from the analysis.

### Period 1

| | |
|---|---|
| Period 1 title | Started first infusion |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Data analyst |

Blinding implementation details:

A nurse note involved in the study in charge of blinding the investigational products, program the automated infusion pump, set up and start the infusion and remove infusion equipment upon completion of administration.
Infusion bags covered with opaque bags, in a manner making it not possible to recognize the number of bags being infused.
The infusion lines covered to mask the yellowish colour of Gelatine.
The data shown on the screen of the automated infusion pump masked to the investigator

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | No |
| **Arm title** | Arm A : reference Sterofundin |

Arm description:

Infusion A: received 1500mls of crystalloid (Sterofundin ISO®)

| | |
|---|---|
| Arm type | Active comparator |
| Investigational medicinal product name | Sterofundin ISO® |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Infusion |
| Routes of administration | Intravascular use |

Dosage and administration details:

1500mls of crystalloid (Sterofundin ISO®

| | |
|---|---|
| **Arm title** | Arm B: 4% Gelaspan |

Arm description:

0.5 Litres of colloid (4% Gelaspan®)

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | 4% Gelaspan |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

0.5 Litres of colloid (4% Gelaspan®)

| | |
|---|---|
| **Arm title** | Arm C: collloid and crystalloid |

Arm description:

0.5 Litres of colloid plus 1 Litre of crystalloid (0.5 Litres 4% Gelaspan ® and 1 Litre of Sterofundin ISO

®)

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Sterofundin ISO® |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Infusion |
| Routes of administration | Intravascular use |

Dosage and administration details:
1500mls of crystalloid (Sterofundin ISO®

| | |
|---|---|
| Investigational medicinal product name | 4% Gelaspan |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:
0.5 Litres of colloid (4% Gelaspan®)

| **Number of subjects in period 1** | Arm A : reference Sterofundin | Arm B: 4% Gelaspan | Arm C: collloid and crystalloid |
|---|---|---|---|
| Started | 10 | 10 | 10 |
| Completed | 10 | 10 | 10 |

**Period 2**

| | |
|---|---|
| Period 2 title | Received all infusions |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator, Monitor, Data analyst |

**Arms**

| | |
|---|---|
| Are arms mutually exclusive? | No |
| **Arm title** | Arm A : reference Sterofundin |

Arm description:
Infusion A: received 1500mls of crystalloid (Sterofundin ISO®)

| | |
|---|---|
| Arm type | Active comparator |
| Investigational medicinal product name | Sterofundin ISO® |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Infusion |
| Routes of administration | Intravascular use |

Dosage and administration details:
1500mls of crystalloid (Sterofundin ISO®

| | |
|---|---|
| **Arm title** | Arm B: 4% Gelaspan |

| | |
|---|---|
| Arm description: | |
| 0.5 Litres of colloid (4% Gelaspan®) | |
| Arm type | Experimental |
| Investigational medicinal product name | 4% Gelaspan |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Infusion |
| Routes of administration | Intravenous use |
| Dosage and administration details: | |
| 0.5 Litres of colloid (4% Gelaspan®) | |
| **Arm title** | Arm C: collloid and crystalloid |
| Arm description: | |
| 0.5 Litres of colloid plus 1 Litre of crystalloid (0.5 Litres 4% Gelaspan ® and 1 Litre of Sterofundin ISO ®) | |
| Arm type | Experimental |
| Investigational medicinal product name | Sterofundin ISO® |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Infusion |
| Routes of administration | Intravascular use |
| Dosage and administration details: | |
| 1500mls of crystalloid (Sterofundin ISO® | |
| Investigational medicinal product name | 4% Gelaspan |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Infusion |
| Routes of administration | Intravenous use |
| Dosage and administration details: | |
| 0.5 Litres of colloid (4% Gelaspan®) | |

| **Number of subjects in period 2** | Arm A : reference Sterofundin | Arm B: 4% Gelaspan | Arm C: collloid and crystalloid |
|---|---|---|---|
| Started | 10 | 10 | 10 |
| Completed | 10 | 10 | 10 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Started first infusion |
| Reporting group description: | |
| Number entered first infusion 10 | |

| Reporting group values | Started first infusion | Total | |
|---|---|---|---|
| Number of subjects | 12 | 12 | |
| Age categorical<br>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) | 12 | 12 | |
| From 65-84 years | 0 | 0 | |
| 85 years and over | 0 | 0 | |
| Age continuous | | | |
| Age | | | |
| Units: years | | | |
| arithmetic mean | 23.9 | | |
| standard deviation | ± 2.8 | - | |
| Gender categorical<br>Units: Subjects | | | |
| Female | 0 | 0 | |
| Male | 12 | 12 | |
| Weight<br>Units: kg | | | |
| arithmetic mean | 74.5 | | |
| standard deviation | ± 5.7 | - | |
| Height<br>Units: Metres | | | |
| arithmetic mean | 1.81 | | |
| standard deviation | ± 0.1 | - | |
| Body Mass Index<br>Units: kg/m squared | | | |
| arithmetic mean | 22.7 | | |
| standard deviation | ± 1.6 | - | |
| Haemoglobin<br>Units: g/L | | | |
| arithmetic mean | 150.1 | | |
| standard deviation | ± 7.6 | - | |
| Haematocrit<br>Units: Percent | | | |

| | | | |
|---|---|---|---|
| arithmetic mean | 43.9 | | |
| standard deviation | ± 1.9 | - | |
| Sodium | | | |
| Units: mmol/L | | | |
| arithmetic mean | 102.9 | | |
| standard deviation | ± 1.3 | - | |
| Serum bicarbonate | | | |
| Units: mmol/L | | | |
| arithmetic mean | 28.2 | | |
| standard deviation | ± 2.2 | - | |
| Serum albumin | | | |
| Units: g/L | | | |
| arithmetic mean | 41.2 | | |
| standard deviation | ± 2.5 | - | |
| Serum osmolality | | | |
| Units: mOsm/kg | | | |
| arithmetic mean | 291 | | |
| standard deviation | ± 2.5 | - | |
| Creatinine | | | |
| Units: umol/L | | | |
| arithmetic mean | 139.6 | | |
| standard deviation | ± 37.9 | - | |
| Calculated blood volume | | | |
| Units: Litres | | | |
| arithmetic mean | 5.2 | | |
| standard deviation | ± 1.6 | - | |

| **Subject analysis sets** | |
|---|---|
| Subject analysis set title | Infusion A versus Infusion B |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Differences between colloid versus crystalloid | |
| Subject analysis set title | Infusion A versus Infusion C |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Difference between colloid versus crystalloid and colloid | |
| Subject analysis set title | Infusion B versus Infusion C |
| Subject analysis set type | Full analysis |
| Subject analysis set description: | |
| Difference between crystalloid and colloid/crystalloid | |

| **Reporting group values** | Infusion A versus Infusion B | Infusion A versus Infusion C | Infusion B versus Infusion C |
|---|---|---|---|
| Number of subjects | 10 | 10 | 10 |
| Age categorical | | | |
| Units: Subjects | | | |
| In utero | | | |
| Preterm newborn infants (gestational age < 37 wks) | | | |
| Newborns (0-27 days) | | | |
| Infants and toddlers (28 days-23 months) | | | |

| | | | |
|---|---|---|---|
| Children (2-11 years)<br>Adolescents (12-17 years)<br>Adults (18-64 years)<br>From 65-84 years<br>85 years and over | 10 | 10 | 10 |
| Age continuous | | | |
| Age | | | |
| Units: years | | | |
| arithmetic mean | 23.9 | 23.9 | 23.9 |
| standard deviation | ± 2.8 | ± 2.8 | ± 2.8 |
| Gender categorical<br>Units: Subjects | | | |
| Female | 0 | 0 | 0 |
| Male | 10 | 10 | 10 |
| Weight<br>Units: kg<br>arithmetic mean<br>standard deviation | ± | ± | ± |
| Height<br>Units: Metres<br>arithmetic mean<br>standard deviation | ± | ± | ± |
| Body Mass Index<br>Units: kg/m squared<br>arithmetic mean<br>standard deviation | ± | ± | ± |
| Haemoglobin<br>Units: g/L<br>arithmetic mean<br>standard deviation | ± | ± | ± |
| Haematocrit<br>Units: Percent<br>arithmetic mean<br>standard deviation | ± | ± | ± |
| Sodium<br>Units: mmol/L<br>arithmetic mean<br>standard deviation | ± | ± | ± |
| Serum bicarbonate<br>Units: mmol/L<br>arithmetic mean<br>standard deviation | ± | ± | ± |
| Serum albumin<br>Units: g/L<br>arithmetic mean<br>standard deviation | ± | ± | ± |
| Serum osmolality<br>Units: mOsm/kg<br>arithmetic mean<br>standard deviation | ± | ± | ± |
| Creatinine<br>Units: umol/L | | | |

| | | | |
|---|---|---|---|
| arithmetic mean<br>standard deviation | ± | ± | ± |
| Calculated blood volume<br>Units: Litres<br>arithmetic mean<br>standard deviation | ± | ± | ± |

## End points

### End points reporting groups

| | |
|---|---|
| Reporting group title | Arm A : reference Sterofundin |
| Reporting group description: Infusion A: received 1500mls of crystalloid (Sterofundin ISO®) | |
| Reporting group title | Arm B: 4% Gelaspan |
| Reporting group description: 0.5 Litres of colloid (4% Gelaspan®) | |
| Reporting group title | Arm C: collloid and crystalloid |
| Reporting group description: 0.5 Litres of colloid plus 1 Litre of crystalloid (0.5 Litres 4% Gelaspan ® and 1 Litre of Sterofundin ISO ®) | |
| Reporting group title | Arm A : reference Sterofundin |
| Reporting group description: Infusion A: received 1500mls of crystalloid (Sterofundin ISO®) | |
| Reporting group title | Arm B: 4% Gelaspan |
| Reporting group description: 0.5 Litres of colloid (4% Gelaspan®) | |
| Reporting group title | Arm C: collloid and crystalloid |
| Reporting group description: 0.5 Litres of colloid plus 1 Litre of crystalloid (0.5 Litres 4% Gelaspan ® and 1 Litre of Sterofundin ISO ®) | |
| Subject analysis set title | Infusion A versus Infusion B |
| Subject analysis set type | Full analysis |
| Subject analysis set description: Differences between colloid versus crystalloid | |
| Subject analysis set title | Infusion A versus Infusion C |
| Subject analysis set type | Full analysis |
| Subject analysis set description: Difference between colloid versus crystalloid and colloid | |
| Subject analysis set title | Infusion B versus Infusion C |
| Subject analysis set type | Full analysis |
| Subject analysis set description: Difference between crystalloid and colloid/crystalloid | |

### Primary: Change in blood volume

| | |
|---|---|
| End point title | Change in blood volume |
| End point description: Change in blood volume over time.<br>The end point values for each time point have been given in the attached table. | |
| End point type | Primary |
| End point timeframe: Blood sampled at baseline and times 30, 60, 90, 120, 180 and 240 minutes | |

| End point values | Arm A : reference Sterofundin | Arm B: 4% Gelaspan | Arm C: collloid and crystalloid | Infusion A versus Infusion B |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 10 | 10 | 10 | 10 |
| Units: Litres | 10 | 10 | 10 | 10 |

| End point values | Infusion A versus Infusion C | Infusion B versus Infusion C | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 10 | 10 | | |
| Units: Litres | 10 | 10 | | |

| Attachments (see zip file) | Blood volume/Blood volume.pdf |
|---|---|

## Statistical analyses

| Statistical analysis title | Change in blood volume |
|---|---|

Statistical analysis description:

For all secondary endpoints the statistical analyses are presented in the attached tables.

| | |
|---|---|
| Comparison groups | Infusion A versus Infusion B v Infusion A versus Infusion C v Infusion B versus Infusion C |
| Number of subjects included in analysis | 30 |
| Analysis specification | Pre-specified |
| Analysis type | non-inferiority[1] |
| P-value | > 0.05 [2] |
| Method | ANOVA |

Notes:

[1] - Repeated measures ANOVA Change in blood volume (A v B, B v C, A v C)

[2] - P > 0.05 for all comparisons.

## Secondary: Change in weight

| End point title | Change in weight |
|---|---|

End point description:

Weight change monitored at 0, 90, 120, 180 and 240 minutes after the start of the infusion
The end point values for each time point have been given in the attached table.

| End point type | Secondary |
|---|---|

End point timeframe:

0, 90, 120, 180, and 240 mins

| End point values | Arm A : reference Sterofundin | Arm B: 4% Gelaspan | Arm C: collloid and crystalloid | Infusion A versus Infusion B |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 10 | 10 | 10 | 10 |
| Units: Kilograms | 10 | 10 | 10 | 10 |

| End point values | Infusion A versus Infusion C | Infusion B versus Infusion C | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 10 | 10 | | |
| Units: Kilograms | 10 | 10 | | |

| Attachments (see zip file) | Change in weight/Weight.pdf |
|---|---|

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change in haematocrit %

| End point title | Change in haematocrit % |
|---|---|

End point description:

The end point values for each time point have been given in the attached table.

| End point type | Secondary |
|---|---|

End point timeframe:

Blood will be sampled at 60, 90, 120, 180 and 240 minutes after the start of the infusion

| End point values | Infusion A versus Infusion B | Infusion A versus Infusion C | Infusion B versus Infusion C | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | Subject analysis set | |
| Number of subjects analysed | 10 | 10 | 10 | |
| Units: percentage | 10 | 10 | 10 | |

| Attachments (see zip file) | Change in haematocrit/Haematocrit.pdf |
|---|---|

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change in albumin %

| End point title | Change in albumin % |
|---|---|

End point description:

The end point values for each time point have been given in the attached table.

| End point type | Secondary |
|---|---|

End point timeframe:

Blood sampled at baseline and times 0, 30, 60, 90, 120, 180 and 240 minutes

| **End point values** | Arm A : reference Sterofundin | Arm B: 4% Gelaspan | Arm C: collloid and crystalloid | Infusion A versus Infusion B |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 10 | 10 | 10 | 10 |
| Units: percentage | 10 | 10 | 10 | 10 |

| **End point values** | Infusion A versus Infusion C | Infusion B versus Infusion C | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 10 | 10 | | |
| Units: percentage | 10 | 10 | | |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Serum sodium mmol/l**

| End point title | Serum sodium mmol/l |
|---|---|

End point description:

The end point values for each time point have been given in the attached table.

| End point type | Secondary |
|---|---|

End point timeframe:

Blood sampled at baseline and times 30, 60, 90, 120, 180 and 240 minutes

| **End point values** | Arm A : reference Sterofundin | Arm B: 4% Gelaspan | Arm C: collloid and crystalloid | Infusion A versus Infusion B |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 10 | 10 | 10 | 10 |
| Units: mmol/l | 10 | 10 | 10 | 10 |

| End point values | Infusion A versus Infusion C | Infusion B versus Infusion C | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 10 | 10 | | |
| Units: mmol/l | 10 | 10 | | |

| Attachments (see zip file) | Serum Sodium/Sodium.pdf |
|---|---|

### Statistical analyses

No statistical analyses for this end point

### Secondary: Aortic flow (ml/s)

| End point title | Aortic flow (ml/s) |
|---|---|

End point description:

The end point values for each time point have been given in the attached table. Comparisons between groups using un-paired t-test, comparison over time using paired t-test.

| End point type | Secondary |
|---|---|

End point timeframe:

MRI at -15, 7, 26, 54 and 83 minutes

| End point values | Arm A : reference Sterofundin | Arm B: 4% Gelaspan | Arm C: collloid and crystalloid | Infusion A versus Infusion B |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 10 | 10 | 10 | 10 |
| Units: ml/s | 10 | 10 | 10 | 10 |

| End point values | Infusion A versus Infusion C | Infusion B versus Infusion C | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 10 | 10 | | |
| Units: ml/s | 10 | 10 | | |

| Attachments (see zip file) | Aortic flow/Aortic flow.pdf |
|---|---|

### Statistical analyses

No statistical analyses for this end point

## Secondary: Serum chloride mmol/l

| End point title | Serum chloride mmol/l |
|---|---|

End point description:

The end point values for each time point have been given in the attached table.

| End point type | Secondary |
|---|---|

End point timeframe:

Blood sampled at baseline and times 30, 60, 90, 120, 180 and 240 minutes

| End point values | Arm A : reference Sterofundin | Arm B: 4% Gelaspan | Arm C: collloid and crystalloid | Infusion A versus Infusion B |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 10 | 10 | 10 | 10 |
| Units: mmol/l | 10 | 10 | 10 | 10 |

| End point values | Infusion A versus Infusion C | Infusion B versus Infusion C | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 10 | 10 | | |
| Units: mmol/l | 10 | 10 | | |

| Attachments (see zip file) | Serum Chloride/Chloride.pdf |
|---|---|

### Statistical analyses

No statistical analyses for this end point

## Secondary: Renal volume (ml)

| End point title | Renal volume (ml) |
|---|---|

End point description:

The end point values for each time point have been given in the attached table. Comparisons between groups using un-paired t-test, comparison over time using paired t-test.

| End point type | Secondary |
|---|---|

End point timeframe:

MRI at -5, 10, 38, 57 and 90 min

| End point values | Arm A : reference Sterofundin | Arm B: 4% Gelaspan | Arm C: collloid and crystalloid | Infusion A versus Infusion B |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 10 | 10 | 10 | 10 |
| Units: ml/s | 10 | 10 | 10 | 10 |

| End point values | Infusion A versus Infusion C | Infusion B versus Infusion C | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 10 | 10 | | |
| Units: ml/s | 10 | 10 | | |

| Attachments (see zip file) | Renal volume/Renal volume.pdf |
|---|---|

### Statistical analyses

No statistical analyses for this end point

### Secondary: Strong ion differences

| End point title | Strong ion differences |
|---|---|

End point description:

The end point values for each time point have been given in the attached table.

| End point type | Secondary |
|---|---|

End point timeframe:

Blood sampled at baseline and times 30, 60, 90, 120, 180 and 240 minutes

| End point values | Arm A : reference Sterofundin | Arm B: 4% Gelaspan | Arm C: collloid and crystalloid | Infusion A versus Infusion B |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 10 | 10 | 10 | 10 |
| Units: mmol/l | 10 | 10 | 10 | 10 |

| End point values | Infusion A versus Infusion C | Infusion B versus Infusion C | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 10 | 10 | | |
| Units: mmol/l | 10 | 10 | | |

| | |
|---|---|
| **Attachments (see zip file)** | Strong io difference/SID.pdf |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Renal artery blood flow

| | |
|---|---|
| End point title | Renal artery blood flow |

End point description:

The end point values for each time point have been given in the attached table. Comparisons between groups using un-paired t-test, comparison over time using paired t-test.

| | |
|---|---|
| End point type | Secondary |

End point timeframe:

MRI at -15, 15, 43, 62 and 95 min

| **End point values** | Arm A : reference Sterofundin | Arm B: 4% Gelaspan | Arm C: collloid and crystalloid | Infusion A versus Infusion B |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Subject analysis set |
| Number of subjects analysed | 10 | 10 | 10 | 10 |
| Units: ml/s | 10 | 10 | 10 | 10 |

| **End point values** | Infusion A versus Infusion C | Infusion B versus Infusion C | | |
|---|---|---|---|---|
| Subject group type | Subject analysis set | Subject analysis set | | |
| Number of subjects analysed | 10 | 10 | | |
| Units: ml/s | 10 | 10 | | |

| | |
|---|---|
| **Attachments (see zip file)** | Renal flow/Renal artery flow.pdf |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

| Adverse events information | |
|---|---|
| Timeframe for reporting adverse events: Throughout trial | |
| Assessment type | Systematic |
| **Dictionary used** | |
| Dictionary name | MedDRA |
| Dictionary version | 1.0 |
| **Reporting groups** | |
| Reporting group title | All groups |

Reporting group description: -

| Serious adverse events | All groups | | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 0 / 10 (0.00%) | | |
| number of deaths (all causes) | 0 | | |
| number of deaths resulting from adverse events | 0 | | |

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

| Non-serious adverse events | All groups | | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | | |
| Cardiac disorders | | | |
| Tachycardia | | | |
| subjects affected / exposed | 2 / 10 (20.00%) | | |
| occurrences (all) | 2 | | |
| General disorders and administration site conditions | | | |
| Excessive sweating | | | |
| subjects affected / exposed | 1 / 10 (10.00%) | | |
| 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? No

### Limitations and caveats

None reported