



Clinical trial results:

Perioperative fluid management in patients receiving major abdominal surgery – Effects of normal saline versus an acetate buffered balanced infusion solution on the necessity of catecholamines for cardiocirculatory support

Summary

| | |
|--------------------------|----------------|
| EudraCT number | 2014-004867-19 |
| Trial protocol | AT |
| Global end of trial date | 28 April 2016 |

Results information

| | |
|-----------------------------------|--|
| Result version number | v1 (current) |
| This version publication date | 26 October 2017 |
| First version publication date | 26 October 2017 |
| Summary attachment (see zip file) | Summary (KATECHOL_Abstract_Eudract.docx) |

Trial information

Trial identification

| | |
|-----------------------|-------------|
| Sponsor protocol code | v1330032015 |
|-----------------------|-------------|

Additional study identifiers

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

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Medical University of Vienna |
| Sponsor organisation address | Waehringerguertel 18-22, Vienna, Austria, |
| Public contact | Head of Department, Clinic for General Anesthesiology, Intensive Care and Pain Management, 0041 140100, anesthesie@meduniwien.ac.at |
| Scientific contact | Head of Department, Clinic for General Anesthesiology, Intensive Care and Pain Management, 0041 140100, anesthesie@meduniwien.ac.at |

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 | 28 August 2017 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 28 April 2016 |
| Global end of trial reached? | Yes |
| Global end of trial date | 28 April 2016 |
| Was the trial ended prematurely? | Yes |

Notes:

General information about the trial

Main objective of the trial:

In this study we want to clarify whether a balanced type fluid solution for perioperative fluid management of patients receiving major abdominal surgery is associated with a lower incidence of need for catecholamines for hemodynamic stability than use of isotonic saline.

Protection of trial subjects:

Patients were monitored closely during and after operation.

Background therapy: -

Evidence for comparator: -

| | |
|---|---------------|
| Actual start date of recruitment | 01 March 2015 |
| 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 | Austria: 60 |
| Worldwide total number of subjects | 60 |
| EEA total number of subjects | 60 |

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) | 45 |
| From 65 to 84 years | 15 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

All patients scheduled for open elective major abdominal surgery and expected to last a minimum of 2 hours were included in the study.

Pre-assignment

Screening details:

Major general surgery includes complex visceral resection, partial or total colectomy, stomach surgery, small bowel resection, open gall-bladder resection, splenektomie, adenektomie and regional lymphnode dissection, major urological or gynecological surgery.

Period 1

| | |
|------------------------------|---------------------------------|
| Period 1 title | periooperative (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 | 0.9% NaCl |
| Arm description: - | |
| Arm type | Active comparator |
| Investigational medicinal product name | 0.9% NaCl |
| Investigational medicinal product code | |
| Other name | normal saline |
| Pharmaceutical forms | Infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

During the perioperative periode patients received a baseline infusion and fluid resuscitation with the study fluid.

| | |
|--|-------------------|
| Arm title | acetate-buffered |
| Arm description: - | |
| Arm type | Active comparator |
| Investigational medicinal product name | Elomel isoton |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

During the perioperative period patients received a continous infusion and fluid resuscitation with the study fluid.

| Number of subjects in period 1 | 0.9% NaCl | acetate-buffered |
|---------------------------------------|-----------|------------------|
| Started | 30 | 30 |
| Completed | 30 | 30 |

Baseline characteristics

End points

End points reporting groups

| | |
|--------------------------------|------------------|
| Reporting group title | 0.9% NaCl |
| Reporting group description: - | |
| Reporting group title | acetate-buffered |
| Reporting group description: - | |

Primary: need for vasocative agents

| | |
|---------------------------------|----------------------------|
| End point title | need for vasocative agents |
| End point description: | |
| End point type | Primary |
| End point timeframe: | |
| during the perioperative period | |

| End point values | 0.9% NaCl | acetate-buffered | | |
|-----------------------------|-----------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 30 | 30 | | |
| Units: 1 | 97 | 67 | | |

Statistical analyses

| | |
|---|------------------------------|
| Statistical analysis title | Wilcoxon |
| Comparison groups | 0.9% NaCl v acetate-buffered |
| Number of subjects included in analysis | 60 |
| Analysis specification | Pre-specified |
| Analysis type | equivalence |
| P-value | < 0.05 |
| Method | Wilcoxon (Mann-Whitney) |

Secondary: cumulative dose of vasoactive agents

| | |
|------------------------|--------------------------------------|
| End point title | cumulative dose of vasoactive agents |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| perioperative period | |

| End point values | 0.9% NaCl | acetate-buffered | | |
|---------------------------------|--------------------------------|------------------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 30 | 30 | | |
| Units: ng/ml/min | | | | |
| number (confidence interval 5%) | 0.000502 (0.0004 to 0.0006) | 0.000044 (0.000034 to 0.000058) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: changes in electrolyte and acid base status

| | |
|------------------------|---|
| End point title | changes in electrolyte and acid base status |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| perioperative periode | |

| End point values | 0.9% NaCl | acetate-buffered | | |
|-----------------------------|-----------------|------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 30 | 30 | | |
| Units: mmol/l | | | | |
| number (not applicable) | 30 | 0 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: unexpected ICU transfers

| | |
|------------------------|--------------------------|
| End point title | unexpected ICU transfers |
| End point description: | |
| End point type | Secondary |
| End point timeframe: | |
| perioperative period | |

| End point values | 0.9% NaCl | acetate- buffered | | |
|-----------------------------|-----------------|----------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 30 | 30 | | |
| Units: count | 1 | 1 | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

From the start of anesthesia to the end of anesthesia.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|---|
| Dictionary version | 1 |
|--------------------|---|

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

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: No serious adverse events were recorded: In this trial, the following events were considered to be efficacy and safety outcomes and are not considered an SAE: hypotension, shock, need for intropes, need for kolloid fluids, need for blood transfusion, need for expected and unexpected intensive care unit transfer.

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