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, adrenalektomie 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