Clinical trial results:
Evaluation of FLuid REsuscitation with Sterofundin ® ISO (Ringerfundin), Plasma-Lyte® or NaCl 0.9%. (FluReS study)

Summary

EudraCT number	2014-001005-41
Trial protocol	BE
Global end of trial date	29 January 2016

Results information

Result version number	v1 (current)
This version publication date	07 June 2024
First version publication date	07 June 2024
Summary attachment (see zip file)	Final Study Report (Final study report.pdf) End Of Trial (2014-001005-41 End of trial.pdf) Doc A (2014-0384.pdf) Protocol (Protocol version 1.docx)

Trial information

Trial identification

Sponsor protocol code	FluReS study

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Ghent University Hospital
Sponsor organisation address	Corneel Heymanslaan 10, Ghent, Belgium, 9000
Public contact	Department of Anaesthethics, Ghent University Hospital, +32 93322142, Freekje.Viaene@gmail.com
Scientific contact	Department of Anaesthethics, Ghent University Hospital, +32 93322142, Freekje.Viaene@gmail.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	Final
Date of interim/final analysis	09 October 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 January 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Primary:
Evaluate impact of fluid bolus with 1 L of Sterofundin, Plasma-Lyte ® and NaCl0.9 on acid-base status according to Stewart (SIDa and SIG).

Protection of trial subjects:

Ethics review and approval, informed consent, supportive care and routine monitoring

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 July 2015
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	Belgium: 99
Worldwide total number of subjects	99
EEA total number of subjects	99

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)	99
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

99 patients were included in the experimetal arms starting from 17-Jul-2015. End of trial notification was dated 29-Jan-2016 and submitted to EC and CA on 19-May-2017

Pre-assignment

Screening details:

Inclusion Criteria:
1. Informed consent patient or legal representative
2. Treating physician decided for fluid bolus of 1 L administered over a 30-60 min time period.
3. Arterial catheter and urinary catheter.

Period 1

Period 1 title	Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Sterofundin

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Sterofundin
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Intravesical solution
Routes of administration	Solution for infusion

Dosage and administration details:

see attachments

Arm title	Plasmalyte

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Plasmalyte
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Intravesical solution
Routes of administration	Solution for infusion

Dosage and administration details:

see attachments

Number of subjects in period 1	Sterofundin	Plasmalyte
Started	52	47
Completed	52	47

Baseline characteristics

Reporting groups	
Reporting group title	Trial

Reporting group description: -

Reporting group values	Trial	Total	
Number of subjects	99	99	
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)	99	99	
From 65-84 years	0	0	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	99	99	
Male	0	0	

End points

End points reporting groups

Reporting group title	Sterofundin
Reporting group description: -	
Reporting group title	Plasmalyte
Reporting group description: -	

Primary: change in chloride concentration

End point title	change in chloride concentration[1]
End point description:	
End point type	Primary
End point timeframe:	
During the study	

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: See attachment

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events: overall trial	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	CTCAE
Dictionary version	5

Reporting groups	
Reporting group title	sterofundin group
Reporting group description: Patients randomised to this group received sterofundin	
Reporting group title	plasmalyte group
Reporting group description: Patients randomised to this group received Plasmalyte	

Serious adverse events	sterofundin group	plasmalyte group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 52 (0.00%)	0 / 47 (0.00%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	sterofundin group	plasmalyte group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 52 (0.00%)	0 / 47 (0.00%)	

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 non-SAE's were recorded for these results

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
30 March 2015	Addition of a 3rd treatment: Plasmalyte

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported