Flures Final Study Report

IDENTIFICATION STUDY	
EC projectn°:	2014/0384
EudraCT n°:	2014-001005-41
Study Title :	Evaluation of fluid resuscitation with sterofundin ISO (Ringerfundin) or NaCl 0.9% (FluReS study)
IDENTIFICATION SPONSOR	
Name sponsor :	UZ Gent – Prof. Hoste
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IDENTIFICATION INVESTIGATOR	
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STUDY DESIGN	
Authors	M. Raes, MD; M. Crivits, MD; M. Hemeryck, MD F. Viaene, MD; D. Benoit MD, PhD; E. Hoste MD, PhD
Study centre(s):	Ghent University hospital/ AZ Sint-Jan Brugge
Publication (reference):	Poster presentation on State of Art Congress London, December 2016
Studied period:	Date of first inclusion: 17/07/2015 Date of site closure: 28/01/2016
Objectives:	To compare the short time effects of a single fluid infusion of saline to that of the balanced solutions Plasmalyte® and Sterofundin®, on serum chloride level, Base-Excess (BE) and the apparent Strong Ion Difference (SIDa).
Methodology:	2 prospective randomized single blinded studies Saline vs. Plasmalyte® (UZ Gent) Saline vs.sterofundin®(AZ ST-JAN Brugge)
Number of patients (planned and analysed):	Planned:100/Included: 99
Diagnosis and main criteria for inclusion:	• Adult • Need for fluid administration • 1-L fluid over a 1-h period. • an arterial line • bladder catheter • informed consent
Test product, dose and mode of administration	Plasmalyte 1000ml (Baxter) I.V.
Duration of treatment:	1 hour
Reference therapy, dose and mode of administration, batch number:	NaCl 0,9% 1000ml (Baxter) I.V.
Duration of treatment	1 hour
STUDY RESULTS	

Criteria for evaluation:	Effect of fluid bolus on serum chloride level, Base-Excess (BE) and the apparent Strong Ion Difference (SIDa).
Randomisation:	After inclusion, patients were randomized by taking a blinded envelope out of the study box.
Patiënts completed	Plasmalyte: 47 NaCl 0,9%: 52
Patiënts excludeded	One patient was excluded out of data analysis because patient died before informed consent could be optained.
Statistical methods:	Non-parametric test between all groups: Kruskal-Wallis Non- parametric test between two groups: Mann-Whitney U
SUMMARY - CONCLUSIONS	Results:

	Saline	Sterofundin	Plasmalyte
N	103	51	47
APACHE II	18 [13;15]	12 [9;21]	16 [12;24]
Cl^-	**T1: +2% [+1%; +3%]**	T1: +1% [-1%; +4%]	T1: 0% [-1%; 0%]
	T4: +2% [0%; +3%]	T4: +1% [-1%; +3%]	T4: 0% [-2%; +1%]
SIDa	**T1: -6% [-8%; -3%]**	T1: -2% [-7%; +3%]	T1: 0% [-4%; +3%]
	T4: -5% [-8%; 0%]	T4: -2% [-6%; +5%]	T4: 0% [-2%; +4%]
BE	**T1: -1 [-1.5; -0.3]**	T1: -0.1 [-0.9; +0.8]	T1: 0.0 [-0.3; +1.0]
	T4: -0.5 [-1.3; +0.5]	T4: +0.1 [-0.9; +1.1]	T4: +0.7 [-0.3; +1.8]

Conclusion:

In ICU patients, a 1-L infusion of saline over 1-h resulted in:

- a small but significant increase of chloride concentration
- decreased SIDa, reflecting change to acidosis
- This effect remained up to 4-h after start of infusion.
- Changes in BE were more discrete, and only observed at the end of infusion.

STUDY SAFETY EVALUATION	
SAE	No SAE's during study

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