



Clinical trial results:

HYDratation and bicarbonate to prevent acute Renal injury after endovascular Aneurysm repair: pilot-feasibility randomized controlled study (HYDRA pilot trial)

Summary

EudraCT number	2015-003073-15
Trial protocol	GB
Global end of trial date	07 August 2017

Results information

Result version number	v1 (current)
This version publication date	13 October 2019
First version publication date	13 October 2019
Summary attachment (see zip file)	HYDRA publication (HYDRA Saratzis.pdf)

Trial information

Trial identification

Sponsor protocol code	0504
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Additional study identifiers

ISRCTN number	ISRCTN12291961
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	University of Leicester
Sponsor organisation address	Glenfield Hospital, Leicester, United Kingdom, LE39QP
Public contact	Athanasios Saratzis, University of Leicester, 0044 07531418104, as875@le.ac.uk
Scientific contact	Athanasios Saratzis, University of Leicester, 0044 07531418104, as875@le.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	29 September 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	07 August 2017
Global end of trial reached?	Yes
Global end of trial date	07 August 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The principal research objective is to examine whether giving a certain type of blood-salt (called bicarbonate) through a vein before we perform a type of surgery to fix swellings (called aneurysms) of the abdominal aorta (the main blood vessel in the abdomen) can prevent damage to the kidneys. Kidney damage, or "Acute kidney injury (AKI)" is a common problem after this type of surgery (the medical term of which is EVAR - that stands for "endovascular repair of and abdominal aortic aneurysm"). Our data suggest that almost 1 in 5 patients having this surgery develop kidney damage. It is well established that this kidney damage (or AKI) can impact on death rates, morbidity, and cost. Bicarbonate, which is a blood-salt, may prevent this. Previous studies in similar types of surgery have shown it to be beneficial in terms of preventing kidney damage. However, it has not been adequately assessed in patients undergoing EVAR so far.

To answer this question we need to perform a large expen

Protection of trial subjects:

As per HRA rules for the United Kingdom.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 February 2016
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: 58
Worldwide total number of subjects	58
EEA total number of subjects	58

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)	0
From 65 to 84 years	58
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Patients screened weekly at multidisciplinary meeting by the screening nurse.

Period 1

Period 1 title	Main (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Control

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	normal saline
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Dispersion for infusion
Routes of administration	Intravenous use

Dosage and administration details:

1ml/kg

Arm title	Intervention
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Arm description: -

Arm type	Experimental
Investigational medicinal product name	Sodium Bicarbonate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate for concentrate for solution for infusion
Routes of administration	Intravascular use

Dosage and administration details:

1ml/kg per patient over 1 hour intravenous infusion as per the study protocol.

Number of subjects in period 1	Control	Intervention
Started	29	29
Completed	29	29

Baseline characteristics

End points

End points reporting groups

Reporting group title	Control
Reporting group description: -	
Reporting group title	Intervention
Reporting group description: -	

Primary: Recruitment rate

End point title	Recruitment rate
End point description: Number of individuals agreeing to take part after they have been screened for inclusion in the study. This is ONLY a feasibility trial.	
End point type	Primary
End point timeframe: 48 hours	

End point values	Control	Intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29	29		
Units: individuals	29	29		

Statistical analyses

Statistical analysis title	Count of individuals taking part
Statistical analysis description: This is a feasibility trial. For the primary endpoint we only counted the n of individuals taking part.	
Comparison groups	Control v Intervention
Number of subjects included in analysis	58
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0 ^[1]
Method	Count
Parameter estimate	Count of individuals
Confidence interval	
level	95 %
sides	2-sided
Variability estimate	Standard deviation

Notes:

[1] - We have not reported a p value as this is a feasibility trial.

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Start of trial until 29th September 2017

Adverse event reporting additional description:

No adverse events occurred.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	1.0
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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: This is a small study with 58 participants of a tested medication/product.

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