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Evaluation of hydration and bicarbonate to prevent acute renal injury after endovascular aneurysm repair (EVAR)

Submission date
13/06/2016

Recruitment status
No longer recruiting

Registration date
29/09/2016

Overall study status
Completed

Last Edited
10/03/2022

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
An abdominal aortic aneurysm (AAA) is a swelling (aneurysm) of the aorta (the main blood vessel that leads away from the heart, down through the abdomen to the rest of the body). In many people, AAAs get bigger overtime, which can eventually lead to rupture (bursting) and death if left untreated. Endovascular Abdominal aortic Aneurysm Repair (EVAR), a type of keyhole surgery, is currently the commonest treatment for patients with an AAA. During the procedure a plastic tube (stent-graft) is inserted through small incisions in the groin. In order to be able to perform this minimally invasive (keyhole) procedure, it is essential to administer a special dye called contrast so that the blood vessels in the abdomen and near the AAA can be seen clearly with the help of x-rays. This dye can however lead affect the function of the kidneys. A potential consequence of EVAR is the development of acute kidney injury (AKI, sudden, serious damage to the kidneys) in up to 20% of individuals. AKI negatively affects patients in a number of ways including prolonging hospital stay and influencing long-term kidney function. Previous studies looking at other types of surgery have shown it is possible to prevent kidney problems by giving the patient a lot of fluid and a blood-salt (called bicarbonate) through a vein before surgery. The aim of this study is to explore whether it is possible to recruit enough patients for the study and at whether hydration and bicarbonate can help prevent AKI in patients undergoing EVAR.

Who can participate?
Adults who are having EVAR surgery for a AAA.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive the current standard of care before their EVAR surgery, which involves receiving fluids for one hour before and for 12 hours after surgery. Those in the second group also receive standard fluid treatment as well as being given a high dose of bicarbonate immediately before their EVAR starts. Participants in both groups undergo the EVAR as per standard practice and receive usual follow up care. Participants are monitored for 48 hours after surgery to look for signs of AKI. In addition, participants are seen after 30 days, to ensure no complications have arisen after the EVAR and participation in the study.

What are the possible benefits and risks of participating?
The only potential benefit of taking part in this study is that bicarbonate may prevent the risk of developing AKI after their EVAR however this is not provent. There are no other direct short term benefits. There is a slight risk that patients may develop an allergic reaction to the fluid or bicarbonate that is given. This is unlikely as the fluids used as part of the trial are fluids that are given to most patients having most types of surgery. Levels of blood salts and acids will be carefully monitored during the procedure and hospital stay.

Where is the study run from?
Leicester Royal Infirmary and University Hospitals Coventry & Warwickshire (UK)

When is the study starting and how long is it expected to run for?
February 2016 to May 2017

Who is funding the study?
Academy of Medical Sciences (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
2015-003073-15

Protocol serial number

30872

Study information

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

Acronym
HYDRA-P

Study objectives
The aim of this study is to:
1. Explore whether participants are willing to undergo treatment randomisation and, the readiness of clinicians to recruit patients in to studies, to inform for a larger randomised controlled trial
2. Assess whether hydration and bicarbonate administration can prevent AKI and renal damage in patients undergoing EVAR, and to determine if this could lead to an adoption in routine clinical practice

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands Central Research Ethics Committee, 12/02/2016, ref: 16/WM/0008

Study design
Randomised; Interventional; Design type: Prevention, Drug, Complex Intervention

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Cardiovascular disease, Primary sub-specialty: Cardiac surgery; UKCRC code/ Disease: Renal/ Other disorders of kidney and ureter

Interventions
Patients undergoing elective endovascular aneurysm repair (EVAR) will be randomised on a 1:1 basis using an online randomisation system (RRAMP) through the Oxford Surgical Interventions Trials Unit (Oxford SITU) following written informed consent for participation in the study prior to the EVAR. A simple randomisation method is used, given that this is a pilot randomised clinical trial. Following consent and randomisation, patients will then be allocated into one of two groups, an intervention or a control group.

Control group: Participants will receive the current NHS standard of care hydration method prior to EVAR which comprises of Hartmann's solution 10mls/kg administered 1 hour prior to anaesthetic induction and a further 12 hours of intravenous hydration with Hartmann's after the EVAR.

Intervention group: Together with the standardised hydration method, participants will receive an additional bolus dose of bicarbonate (1 mmol/kg or 1 ml/kg of an 8.4% solution) over 60 minutes, given at anaesthetic induction. During the procedure all participants will receive intra-operative fluids with the aim of maintaining mean arterial pressure within 80% of the baseline for 90% of the time. Post-operatively, 2mls/kg/hr of intravenous crystalloid will be given for 12 hours, identical to the control group.

All medication will be administered intravenously using a cannula and patient care will be overseen by an anaesthetist during the EVAR.

Urine and venous blood samples will be collected prior to surgery, during the EVAR procedure and post-surgery at 6, 24, 48 hours, day of discharge and finally at 30 days at the follow-up appointment. These samples will be used to measure serum creatinine, estimated GFR, subclinical urine markers, pH levels, bicarbonate levels and haemoglobin levels. Urine output of all patients will be recorded during the hospital stay up until they are discharged. The overall follow-up duration is 30 days (after the EVAR has taken place).

Intervention Type
Other

Primary outcome(s)
Recruitment rate is recorded as the number of eligible participants who consent to take part in the study in the 12 month recruitment period.

Key secondary outcome(s))
Proportion of patients developing AKI within 48 hours after completion of EVAR, as determined by NICE guidelines and assessing serum creatinine levels using clinical observations and reviewing medical records.

Completion date
30/05/2017

Eligibility

Key inclusion criteria
1. Those undergoing an elective endovascular infra-renal abdominal aortic aneurysm repair, for a non-ruptured or leaking aneurysm
2. Aged 18 years and over
3. Able to provide informed consent for the EVAR and participation in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
58

Key exclusion criteria
1. Emergency abdominal aortic aneurysm repair
2. Leaking or ruptured aneurysm
3. Age<18 years
4. Established cardiac failure with functional status >NYHA III (severe heart failure)
5. Allergy to contrast medium or sodium bicarbonate
6. Pregnancy or lactation (pregnancy test is standard practice at baseline)
7. Juxtarenal or suprarenal aneurysm
8. Solitary kidney
9. Administration of intra-venous or intra-arterial contrast <2 days prior to EVAR
10. Previous open AAA or iliac aneurysm repair
11. Surgery within 1 month before EVAR
12. Major trauma within 1 month before EVAR
13. Established metabolic or respiratory alkalosis 14. Patient receiving chemotherapy, radiotherapy or steroid therapy
15. Life expectancy less than 1 year
16. Patient undergoing renal dialysis for established renal failure
17. Patient receiving nephrotoxic medication for 48 hours prior to EVAR
18. Patient unwilling or unable to provide informed consent
19. Participation in other interventional clinical trial 1 month prior to commencing HYDRA-P
20. Established pulmonary oedema at baseline
21. Hyperventilation
22. Hypernatraemia
23. Systolic blood pressure exceeding 200mHg at baseline
24. Unable to understand and provide consent in English

Date of first enrolment
01/04/2016

Date of final enrolment
28/02/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Leicester Royal Infirmary
Robert Kilpatrick Clinical Sciences Building
2nd Floor
Leicester
United Kingdom
LE1 5WW

Study participating centre
University Hospitals Coventry & Warwickshire (UHCW)
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CV2 2DX

Sponsor information

Organisation
University of Leicester

ROR
https://ror.org/04h699437

Funder(s)

Funder type
Research organisation

Funder Name
Academy of Medical Sciences

Alternative Name(s)
The Academy of Medical Sciences

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the Oxford Surgical Interventions Trials Unit, when the study is complete.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/02/2018	10/03/2022	Yes	No
Basic results			17/06/2020	No	No
HRA research summary			28/06/2023	No	No