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Does giving kidney donors intravenous fluids the night before kidney donation make any difference?

Submission date
25/03/2015

Recruitment status
No longer recruiting

Registration date
20/04/2015

Overall study status
Completed

Last Edited
23/01/2017

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Donated kidneys are extremely precious, and we want to make sure that they are transferred from the donor to the recipient in the best possible condition. People donating kidneys can be treated in two different ways – sometimes they are admitted into hospital overnight and given fluid through a drip in their arm, and sometimes they come into hospital in the morning of the surgery. So far, neither of these approaches has been shown to be better than the other. However, there now exists a new blood test which looks at the levels of a protein called N-GAL in the blood. It is much more sensitive at measuring how well the kidneys are working than older tests. The purpose of the study is to compare these two approaches. This may help determine whether one of these approaches enables the kidney to be transplanted in a better condition, or whether there is no difference between them. To do this, the new blood test will be used. Also, during the operation, as well as normal monitoring, an extra monitoring device will be used. It will be used to monitor the donor's heart and the way in which blood is pumped around the body, to see whether this is affected by the different approaches.

Who can participate?
Anyone who is donating a kidney at the Western Infirmary (or the South Glasgow University Hospital, when the department moves there) while this trial is going on.

What does the study involve?
As a kidney donor you will be admitted to hospital the night before the operation as normal, and randomly allocated to one of two groups. One group will be given fluids through a drip in the arm, whereas the other group will not. Both groups will have access to water and be able to drink freely overnight. Just before and during the operation, in addition to the standard monitoring, four small electrode stickers will be applied to your chest and neck to assess blood flow and a probe placed on your fingers to measure your blood pressure continuously. These additional monitors will be applied in the anaesthetic room immediately before your surgery. The information gained from these measurements will not affect your care during the operation, which will be undertaken in the standard fashion. Several blood samples will be collected for the few days after the operation. The blood will be drawn at the same time as the routine samples

that would normally be taken as part of your care. This means that you shouldn't be subject to extra needle punctures of your skin. During the operation, two blood samples will be taken from you, but these will be taken while you are under the anaesthetic so you will not feel them. Altogether, maximum of 12 blood samples will be collected. These will each be a maximum of 20 ml (about one tablespoon). These samples will not have your name or personal details recorded on them. They will be transferred to a laboratory at Glasgow University, analysed and stored there in a sample bank. The samples may subsequently be re-analysed in future approved research. We will record information about your progress for one year after the transplant. This information will be stored in an anonymised way – it will not contain your name or personal details.

What are the possible benefits and risks of participating?
As the two groups of patients are being treated slightly differently, it might be that one of the groups has a slightly different outcome. The results of this study may eventually help improve the outcomes for kidney transplantation in the future. No significant risks or disadvantages are anticipated. Although during the operation the donor will be attached to an extra monitor, the data generated by this monitor will have no impact on your care. You will need to provide blood samples as detailed above.

Where is the study run from?
The study will be run from the Western Infirmary, Glasgow, until the department is transferred to the new South Glasgow University Hospital, where the study will continue to run.

When is the study starting and how long is it expected to run for?
January 2015 to January 2017

Who is funding the study?
Transplant and Renal Failure Surgery Endowment Fund (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A Comparison of the effects of Oral vs INtravenous hydration on Subclinical acute kidney injury: a randomised controlled trial

Acronym
COINS

Study objectives
The use of preoperative intravenous fluids will result in a measurable improvement in intraoperative haemodynamics and a decrease in donor subclinical acute kidney injury, as measured by N-GAL.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West of Scotland Research Ethics Committee 3, West of Scotland Research Ethics Service, 27/01/2015, ref: 14/WS/1160.

Study design
Prospective single-centre single-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Live kidney donors

Interventions
Patients will be randomly assigned to one of two groups using a computer-generated randomisation schedule.

Preoperative Intravenous Fluid Group
The evening prior to surgery (day -1), between midnight and 8 am, patients in this group will receive three litres of crystalloid solution, IV, in addition to unrestricted oral fluid in line with the pre-operative fasting guidelines produced by the Association of Anaesthetists of Great Britain and Ireland.

No Preoperative Intravenous Fluid Group
Patients in this group will also be admitted on the evening prior to surgery (day -1) but will not be given intravenous fluids. They will therefore only receive unrestricted oral fluids in accordance with The Association of Anaesthetists of Great Britain and Ireland fasting guidelines.

Intervention Type
Other

Primary outcome measure
Day +1 acute kidney injury (as measured by N-GAL)

Secondary outcome measures
1. Day 1 change in donor N-GAL from baseline
2. Donor renal function (serum creatinine and eGFR) day 1-4, week 6 and 1 year, as is standard procedure
3. Donor BNP (Day -1, Day 0, Day 1)
4. Recipient change in N-GAL from baseline
5. Recipient serum creatinine and eGFR at 6 weeks and 1 year
6. Delayed graft function (DGF) – defined as use of dialysis in the first week postoperatively
7. 1-year graft and patient survival in recipient
8. Intraoperative haemodynamics (including blood pressure, heart rate, stroke volume, cardiac index and systemic vascular resistance index) and response to fluid challenge
9. N-GAL levels in blood obtained from renal vein during retrieval and implantation surgery
10. Perioperative mortality
11. Perioperative fluid balance
12. Perioperative complications (including cardiorespiratory complications, time to first bowel motion, infective complications, length of hospital stay, readmission)
13. Donor sleep quality

Overall study start date
01/03/2014

Completion date
30/01/2017

Eligibility

Key inclusion criteria
1. Adult patients aged >18 years of age undergoing live donor hand-assisted laparoscopic nephrectomy eligible to participate
2. Consent to participate given
3. English-speaking or appropriate translation facilities to allow for consent to be valid
4. Living donor transplant in Western Infirmary, Glasgow
5. Transplant taking place between dates of the trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
86

Key exclusion criteria
1. Patients undergoing open nephrectomy
2. Patients unable/unwilling to consent

Date of first enrolment
30/01/2015

Date of final enrolment
30/01/2017

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Western Infirmary
Dumbarton Road
Glasgow
United Kingdom
G11 6NT

Study participating centre
South Glasgow University Hospital
Glasgow
United Kingdom
G51 4SX

Sponsor information

Organisation
NHS Greater Glasgow and Clyde

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Transplant and Renal Failure Surgery Endowment Fund

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	19/01/2017		Yes	No
HRA research summary			28/06/2023	No	No