

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

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| <b>Submission date</b><br>25/03/2015   | <b>Recruitment status</b><br>No longer recruiting            | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol            |
| <b>Registration date</b><br>20/04/2015 | <b>Overall study status</b><br>Completed                     | <input type="checkbox"/> Statistical analysis plan<br><input type="checkbox"/> Results                       |
| <b>Last Edited</b><br>23/01/2017       | <b>Condition category</b><br>Urological and Genital Diseases | <input type="checkbox"/> Individual participant data<br><input type="checkbox"/> 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?

Marc Clancy

Marc.Clancy@ggc.scot.nhs.uk

## Contact information

### Type(s)

Scientific

### Contact name

Mr Marc Clancy

### Contact details

Renal Transplant Unit

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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**  
c/o Dr Maureen Travers  
Research Coordinator  
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Tennent Institute  
38 Church Street  
Glasgow  
Scotland  
United Kingdom  
G11 6NT

**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? |
|--------------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a>     | protocol | 19/01/2017   |            | Yes            | No              |
| <a href="#">HRA research summary</a> |          |              | 28/06/2023 | No             | No              |