

A randomised trial of antibiotics in laparoscopic donor nephrectomy

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| Submission date 08/01/2015 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 09/01/2015 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 28/05/2020 | Condition category Urological and Genital Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Plain English summary under review

Contact information

Type(s)

Scientific

Contact name

Dr Bynvant Sandhu

Contact details

Renal Unit
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Additional identifiers

ClinicalTrials.gov (NCT)

NCT02089568

Clinical Trials Information System (CTIS)

2012-000942-36

Protocol serial number

13238

Study information

Scientific Title

Are prophylactic antibiotics necessary before laparoscopic living kidney donation? A double blind, randomised, controlled trial

Acronym

PoWAR

Study objectives

Around two-thirds of all kidney transplants in the UK are performed using kidneys from living kidney donors; these are individuals who have volunteered to donate one of their kidneys. Every attempt is made to minimise the risk of complications in these patients, who do not have any need to undergo surgery.

We know that a significant number (10-15%) of these patients will have infections (such as infections of their surgical wound, urinary infections or chest infections) after surgery. These infections may lead to a longer time spent in hospital, re-attendance at the hospital, GP or local Emergency department after discharge and a longer recovery time. Most donors are working and a delay in returning to work is important to them. Infections may cause significant discomfort and anxiety. Costs are increased (threefold) due to the longer hospital stay. A single dose of antibiotics given at the start of surgery is often used to prevent surgical site infections. However, whether this is beneficial for living donors has not been tested. Patients undergoing bowel surgery for example, are usually ill (donors are healthy) and bowel surgery is regarded as a 'contaminated' operation, due to the bacteria within the gut. Living kidney donation however may not involve potential contamination with bacteria. If antibiotics are used unnecessarily, consequences include side effects, such as diarrhoea and allergic reactions (which can be serious), the spread of resistance to antibiotics, and an extra cost. We are therefore proposing a trial which will compare the risk of infections, side effects, hospital stay and costs in those who receive a dose of antibiotics and those who receive a placebo (which would be an injection of salt water). The patients will be randomised by a computer to one or other treatment, and patients will be followed for one month after surgery. We expect that the findings will be easy to implement across the UK for living donors.

Ethics approval required

Old ethics approval format

Ethics approval(s)

12/LO/0877

Study design

Randomised; Interventional;

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Topic: Renal disorders; Subtopic: Renal disorders; Disease: All Renal disorders

Interventions

A single intravenous dose (1.2g) of the IMP (or placebo) will be given at induction of anaesthesia.

Intervention Type

Drug

Phase

Not Applicable

Primary outcome(s)

The primary outcome measure will be a composite endpoint of any infection; this will include surgical site infections as well as urinary tract, respiratory and any other infections, within 30 days of surgery.

Key secondary outcome(s)

1. Ultrasonic evidence of wound healing
2. Length of hospital stay
3. Readmission rates
4. Antibiotic associated side effects (including diarrhoea and allergic reactions), return to work and normal activities
5. Quality of life and relative costs

Completion date

30/04/2016

Eligibility**Key inclusion criteria**

1. All adult patients (over 18 years) undergoing hand-assisted laparoscopic donor nephrectomy, who have given written informed consent, will be included
2. Patients whose first language is not English will be included; they comprise a significant part of our patient population and we will use translation services as is our normal practice
3. Women of child-bearing age taking adequate contraception will be included

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

295

Key exclusion criteria

1. Patients with a known allergy to penicillin or other antibiotics
2. Patients with MRSA colonisation
3. Participation in another investigational study within the previous 90 days
4. Pregnant or breastfeeding women

Date of first enrolment

01/01/2013

Date of final enrolment

31/12/2015

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Renal Unit

Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Sponsor information

Organisation

Guy's and St. Thomas' NHS Foundation Trust

ROR

<https://ror.org/00j161312>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health Research

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| Basic results | | | 28/05/2020 | No | No |
| HRA research summary | | | 28/06/2023 | No | No |