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A randomised trial of antibiotics in laparoscopic donor nephrectomy

Submission date	Recruitment status	[_] Prospectively registered
08/01/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
09/01/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
28/05/2020	Urological and Genital Diseases	

Plain English summary of protocol
Plain English summary under review

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2012-000942-36

IRAS number

ClinicalTrials.gov number
NCT02089568

Secondary identifying numbers
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 indviduals 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/01/2013

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 284; UK Sample Size: 284

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
England

United Kingdom

Study participating centre
Renal Unit
Guy's Hospital
Great Maze Pond
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SE1 9RT

Sponsor information

Organisation

Guy's and St. Thomas' NHS Foundation Trust

Sponsor details
Research & Development Dept 2nd Floor Conybeare House
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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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