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Single-dose prophylaxis antibiotic in laparoscopic living donor nephrectomy

Submission date
15/05/2016

Recruitment status
No longer recruiting

Registration date
20/12/2016

Overall study status
Completed

Last Edited
02/04/2019

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
In a laparoscopic living donor nephrectomy (LLDN), a kidney is transplanted from a living donor to a patient. Antibiotics are often given to patients undergoing surgery to prevent infection (prophylactic antibiotics). The inappropriate use of antibiotics increases the risk of antibiotic resistance, so prophylactic antibiotics should be used for the shortest possible period. The aim of this study is to compare the effectiveness and safety of a single dose of antibiotics and 3 days of antibiotics in patients undergoing LLDN.

Who can participate?
Patients undergoing laparoscopic living donor nephrectomy

What does the study involve?
Participants are randomly allocated to one of two groups. The single dose group are given one dose of antibiotics before undergoing surgery. The 3 days group are given antibiotics before undergoing surgery and after the surgery continue to receive antibiotics twice daily for three days. The incidence of infection after the operation is compared between the two groups.

What are the possible benefits and risks of participating?
The results of this study could improve the way we use prophylactic antibiotics. There are minimal additional risks compared with standard LLDN.

Where is the study run from?
Cipto Mangunkusumo Hospital (Indonesia)

When is the study starting and how long is it expected to run for?
April 2015 to August 2015

Who is funding the study?
Cipto Mangunkusumo Hospital (Indonesia)

Who is the main contact?
Dr Andry Giovanny

Contact information

Type(s)
Scientific

Contact name
Dr Andry Giovanny

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
855/UN2.F1/Etik/2014

Study information

Scientific Title
Single dose prophylaxis antibiotic in laparoscopic living donor nephrectomy: a double-blind randomized controlled trial study

Study objectives
Proper antibiotic use is a concern due to the increase of antibiotic resistance. Standardized techniques and prophylactic antibiotics are widely used in urologic surgeries, but the prolonged administration of antibiotic after an operation has not been fully studied, especially clean contaminated surgery such as laparoscopy living donor nephrectomy (LLDN). This study aimed to evaluate the efficacy and safety of single-dose prophylactic antibiotic in laparoscopic live donor nephrectomy operation in Cipto Mangunkusumo Hospital, Jakarta.

Ethics approval required
Old ethics approval format

Ethics approval(s)
855/UN2.F1/Etik/2014

Study design
Randomized controlled trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Kidney transplantation

Interventions
The patients were randomly divided into two groups. The single dose group were given 1 g cefoperazone as prophylactic antibiotics intravenously 30 minutes before surgery and after that water for injection was injected as a placebo twice daily for 3 days. The 3 days group were also given cefoperazone before surgery and continued twice daily for three days. When the duration of surgery exceeded 3 hours, we administered another extra 1 g of cefoperazone, considered as prophylactic. The incidence of post-operative infection and contributing factors were compared between the two groups. Physical examination was carried out daily during hospitalization, and on the 10th day after surgery at the scheduled follow-up consultation.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Cefoperazone

Primary outcome measure
Local infection at the 1st and 10th days after surgery. Local signs of infection include one of the following criteria: purulent discharge from the wound, tenderness/swelling/erythema, positive culture from a specimen taken from the wound with proper technique.

Secondary outcome measures
Systemic infection at the 1st and 10th days after surgery. The systemic signs of infection must meet both criteria: tachycardia (>100 beats/minutes) with temperature > 3oC and leukocytosis (>10.000 /mL).

Overall study start date
01/04/2015

Completion date

31/08/2015

Eligibility

Key inclusion criteria
Patients undergoing laparoscopic living donor nephrectomy

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
Having infection

Date of first enrolment
01/04/2015

Date of final enrolment
01/07/2015

Locations

Countries of recruitment
Indonesia

Study participating centre
Cipto Mangunkusumo Hospital
Department of Urology
University of Indonesia
DIponegoro st. No 71
Daerah Khusus Ibukota Jakarta
Indonesia
15320

Sponsor information

Organisation

Cipto Mangunkusumo Hospital (Indonesia)

Sponsor details
Jl. Diponegoro No. 1
Jakarta
Indonesia
15320

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05am7x020

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Cipto Mangunkusumo Hospital (Indonesia)

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 expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		07/07/2016	02/04/2019	No	No