

Single-dose prophylaxis antibiotic in laparoscopic living donor nephrectomy

Submission date 15/05/2016	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 20/12/2016	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 02/04/2019	Condition category Surgery	☐ 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 Giovanni

Contact information

Type(s)

Scientific

Contact name

Dr Andry Giovanny

Contact details

Jl. Diponegoro No 71

Jakarta

Indonesia

115320

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomized controlled trial

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

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 > 38°C and leukocytosis (>10,000 /mL).

Completion date

31/08/2015

Eligibility

Key inclusion criteria

Patients undergoing laparoscopic living donor nephrectomy

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/05am7x020>

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Cipto Mangunkusumo Hospital (Indonesia)

Results and Publications

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