

To investigate if administration of methylprednisone before surgery could decrease the incidence of urosepsis postoperative in patients with high risks undergoing percutaneous nephrolithotomy

Submission date 02/05/2018	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 21/05/2018	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 10/10/2022	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Percutaneous nephrolithotomy is a surgical procedure to remove kidney stones. Infective complications after this surgery are very common. Among them the spread of a urinary tract infection to the blood stream (urosepsis) is the most severe and sometimes it can lead to the death of patients. In patients with history of urinary tract infection, toxins produced by bacteria (bacteriotoxins) such as endotoxin are absorbed into the circulation during the operation. These toxins can induce great and complex inflammatory response. The patients may undergo high fever, increased heart rate (tachycardia), fast breathing, increased numbers of white blood cells (leukocytosis) and signs of organ injury. These signs are known as urosepsis. It might be effective to prevent urosepsis to inhibit this excessive immune response and inflammation.

Methylprednisone is a drug that has been used in clinic widely to reduce the immune system reaction and decrease inflammation.

This study aims to evaluate how well methylprednisone works in preventing urosepsis.

Who can participate?

Adults aged over 17 years undergoing percutaneous nephrolithotomy

What does the study involve?

Participants are randomly allocated to one of two groups. Those in the first group receive the drug methylprednisone through a tube in their vein, before the operation. Those in the second group receive a dummy (placebo) substance called saline before the operation. After surgery, participants are followed up until they are discharged from the hospital.

What are the possible benefits and risks of participating?

There is no immediate direct benefit to those taking part. But there should be benefits to future patients because the results of the study are likely to influence the guideline to prevent

urosepsis around the time of an operation.

The possible risks of methylprednisone administered are water-sodium retention, electrolyte (chemicals forming electrically charged particles in the body, such as sodium) disturbances and accumulation of fluid in tissues within the body (edema). In consideration of the low dose used in this study, the harmful response of methylprednisone might be little if any. What is more, the investigators care for the participants intensively throughout the period of operation and manage any harmful response in time.

Where is the study run from?

Changhai Hospital of Shanghai (China)

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

May 2018 to March 2020

Who is funding the study?

National Natural Science Foundation of China (China)

Who is the main contact?

Prof. Yi Liu (Scientific)

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Contact information

Type(s)

Scientific

Contact name

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200433

Additional identifiers

Protocol serial number

01

Study information

Scientific Title

The effectiveness of methylprednisone to prevent urosepsis after percutaneous nephrolithotomy in patients with high risk

Study objectives

It is hypothesised that methylprednisone would decrease the incidence of urosepsis after percutaneous nephrolithotomy in patients with high risk

Ethics approval required

Old ethics approval format

Ethics approval(s)

Shanghai Changhai Hospital Ethics Committee, 17/05/2018, CHEC2018-060

Study design

Perspective randomized single-blind placebo-controlled study

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Urosepsis after percutaneous nephrolithotomy

Interventions

Current interventions as of 24/09/2018:

After induction of general anesthesia, participants are allocated to one of two groups using stratified block randomization, with the stratified factor being gender. In group M, the participants are given methylprednisone 40mg intravenously before the operation. In group C, the participants are given an equal volume of normal saline.

All participants are followed up until they are discharged.

Previous interventions:

After induction of general anesthesia, participants are divided into two groups according to the method of random number table. In group M, the participants are given methylprednisone 40mg intravenously before the operation. In group C, the participants are given an equal volume of normal saline.

All participants are followed up until they are discharged.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Methylprednisone

Primary outcome(s)

Incidence of urosepsis is recorded postoperatively by the investigator

Key secondary outcome(s))

Incidence of systemic inflammatory response syndrome (SIRS) and uroseptic shock is recorded postoperatively by the investigator

Completion date

01/03/2020

Eligibility

Key inclusion criteria

1. Scheduled to undergo elective percutaneous nephrolithotomy
2. History of urinary tract infection
3. Once urine culture positive
4. Count of white blood cell in urine $\geq 500/\mu\text{l}$
5. Aged over 17 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

80

Key exclusion criteria

1. Allergic to methylprednisone
2. Use corticosteroids within one month before the operation
3. Use immunodepressant
4. Fasting blood glucose more than 11 mmol/L
5. Active digestive tract ulcer
6. Emergency surgery
7. Pregnant women

Date of first enrolment

01/06/2018

Date of final enrolment

30/12/2019

Locations

Countries of recruitment

China

Study participating centre
Changhai Hospital of Shanghai
NO.168 Changhai Road
Shanghai
China
200433

Sponsor information

Organisation
Changhai Hospital of Shanghai

ROR
<https://ror.org/02bjs0p66>

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhùi, , NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request using the contact details above.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/01/2021	10/10/2022	Yes	No
Basic results		06/04/2021	06/04/2021	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes