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

<b>Submission date</b> 02/05/2018	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered	
		☐ Protocol	
Registration date 21/05/2018	Overall study status Completed	Statistical analysis plan	
		[X] Results	
<b>Last Edited</b> 10/10/2022	Condition category Infections and Infestations	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 unitary 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) ziboliuyi@yeah.net

# Contact information

# Type(s)

Scientific

#### Contact name

Prof Yi Liu

#### **ORCID ID**

http://orcid.org/0000-0002-1804-3602

#### Contact details

The department of anesthesiology Changhai Hospital of Shanghai NO.168 Changhai road Shanghai China 200433

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

01

# Study information

#### Scientific Title

The effectiveness of methylprednisone to pevent 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

#### Secondary study design

Randomised controlled trial

# Study setting(s)

Hospital

# Study type(s)

Prevention

# 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

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 measure

Incidence of urosepsis is recorded postoperatively by the investigator

# Secondary outcome measures

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

#### Overall study start date

01/05/2018

# 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 ≥ 500/ul
- 5. Aged over 17 years

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Sex

Both

#### Target number of participants

100 cases, 50 cases in each group

#### 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

# Sponsor details

NO.168 Changhai Road Shanghai China 200433

# Sponsor type

Hospital/treatment centre

#### **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 Wěiyuánhuì, NSFC, NNSF, NNSFC

# **Funding Body Type**

Government organisation

# **Funding Body Subtype**

National government

#### Location

China

# **Results and Publications**

# Publication and dissemination plan

Planned publication in a high impact peer-reviewed journal.

# Intention to publish date

06/04/2020

# 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?
Basic results		06/04/2021	06/04/2021	No	No
Results article		01/01/2021	10/10/2022	Yes	No