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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

Registration date
21/05/2018

Overall study status
Completed

Last Edited
10/10/2022

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Contact information

Type(s)
Scientific

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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
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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