

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Investigating the effect of oral theophylline on complications caused by double J: A Double Blind Clinical Trial

Protocol summary

Study aim

Investigating the effect of oral theophylline on complications caused by double J: A Double Blind Clinical Trial

Design

The study is an interventional study in two control groups (30 people) and intervention (30 people), double-blind (patient and researcher), phase 3, parallel and therapeutic.

Settings and conduct

This clinical trial will be conducted in Sina Hospital, Urology Research Center, on 60 patients. The first group: Double G treatment along with placebo (30 people). Second group: Double G treatment group along with theophylline (30 people).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing trans ureteral lithotripsy Patients under the endoscopic ureter For other cases that have a bleeding effect, double G is installed for them, Written and informed consent from patients
Exclusion criteria: Symptoms of prostatitis/ asthma/ being a smoker Diabetes Gastrointestinal discomfort Insomnia and tremors Taking potassium-sparing diuretics Taking digoxin in patients with heart problems Taking levodopa Taking calcium supplements at the same time/ Taking spironolactone tablets Previous history of hyperkalemia Taking triamterene Taking tablets Amiloride High blood potassium and pregnancy

Intervention groups

Treatment group, Double G, along with the use of Teolite with the generic name of Theophylline Retard with a dose of 200 mg, Obidi company, 30 tablets, one daily for one month. Treatment group, double G, and placebo (a capsule containing sugar that looks similar to a probiotic capsule and is prescribed for 4 weeks).

Main outcome variables

Investigating infection and hematuria caused by double G due to the use and non-use of theophylline along with double G stent placement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190624043991N22**

Registration date: **2023-11-19, 1402/08/28**

Registration timing: **prospective**

Last update: **2023-11-19, 1402/08/28**

Update count: **0**

Registration date

2023-11-19, 1402/08/28

Registrant information

Name

Seyed Mohammad Kazem Aghamir

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6634 8560

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mkaghamir@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-31, 1402/11/11

Expected recruitment end date

2025-01-30, 1403/11/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of oral theophylline on complications caused by double J: A Double Blind Clinical Trial

Public title

Investigating the effect of oral theophylline on complications caused by double J

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing trans ureteral lithotripsy Patients under the endoscopic ureter For other cases that have a bleeding effect, double G is installed for them. Written and informed consent from patients

Exclusion criteria:

Symptoms of prostatitis/ asthma/ being a smoker Diabetes Gastrointestinal discomfort Insomnia and tremors Taking potassium-sparing diuretics Taking digoxin in patients with heart problems Taking levodopa Taking calcium supplements at the same time/ Taking spironolactone tablets Previous history of hyperkalemia Taking triamterene Taking tablets Amiloride High blood potassium and pregnancy

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The present study is a double-blind, randomized clinical trial. The researcher and the participant will not know about the randomization method. For randomization, the balanced block randomization method is used to generate four blocks. Intervention group A and control group B have been determined. According to the randomization method, we expect the two groups to differ by a maximum of 2 people in terms of the number of people assigned. After the methodologist prepares the randomization sequence using the Sealdenvelop online site, the generated sequence will be available to a technician outside the research team. Quadruple blocks (A or B) are placed in envelopes. After the arrival of the first patient with the inclusion criteria, the envelopes are randomly selected, and the type of patient group is informed to the research team through a trained technician. Based on the randomly selected envelope, the patient is placed in the group (Double G plus placebo: 30 patients) or (Double G plus theophylline: 30 patients).

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study is a double-blind, randomized clinical trial study. The researcher and the participant will not know how to be placed in the control or intervention groups. The present study is a double-blind, randomized clinical trial study. The researcher and the participant will not know how to be placed in the control group: Double G plus placebo, and the treatment group: Double G plus theophylline. Placebo, a capsule containing sugar resembling a probiotic capsule, is prescribed for 4 weeks.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committees in Medical Medical Research

Street address

Room 604, Sixth Floor, Central Staff Building, Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2023-04-15, 1402/01/26

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1402.007

Health conditions studied

1

Description of health condition studied

Ureteral stone

ICD-10 code

N21

ICD-10 code description

Calculus of lower urinary tract

Primary outcomes

1

Description

investigating the double J infection brought on by double J stent placement and theophylline usage or non-use

Timepoint

Immediately after leaving double J stent

Method of measurement

Laboratory diagnosis

Secondary outcomes

1

Description

Hematuria after surgery from the operation site

Timepoint

Immediately after surgery

Method of measurement

The number of wet gases

Intervention groups

1

Description

Treatment group, Double G, along with the use of Teolite with the generic name of Theophylline Retard with a dose of 200 mg, Obeidi Pharmaceutical Company, 30 tablets, one daily for one month

Category

Treatment - Drugs

2

Description

Treatment group, double G, and placebo (a capsule containing sugar that looks similar to a probiotic capsule and is prescribed for 4 weeks), Obeidi Pharmaceutical Company

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Mohammad Kazem Aghamir

Street address

Urology Research Center - Sina Hospital - Hassan Abad St. - Tehran - Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Sixth Floor, Central University, Quds Ave., Keshavarz Boulevard, Tehran, Iran.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akram Mirzaei

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

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Person responsible for scientific inquiries

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Specialist
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
Dr Akram Mirzaei
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Demographic information anonymously

When the data will become available and for how long

One year after publication

To whom data/document is available

En Researchers working in academia, physicians, surgeons and hospitals

Under which criteria data/document could be used

En Any analysis can be done with the consent of the main researcher

From where data/document is obtainable

Sina Hospital, Urology Research Center, Head of Urology Research Center: Dr. Seyed Mohammad Kazem Aghamir 00982166348560

What processes are involved for a request to access data/document

En After reviewing the information by the administrator and epidemiologist, the patient information will be available for the applicant by the provision of a patient's privacy.

Comments