

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Evaluation of the analgesic effect of oral administration of Acetaminophen + Oxycodone after extracorporeal shock with shock waves

Protocol summary

Study aim

Evaluation of the analgesic effect of oral administration of Acetaminophen + Oxycodone after extracorporeal shock with shock waves

Design

A clinical trial with two groups of patients: parallel, therapeutic, blanced block randomization, single blind (patient). 150 patients referred to Sinai Hospital.

Settings and conduct

150 patients at Sina Hospital. blanced block randomization, single blind(patient). Patients are divided into two groups: Group 1: Acetaminophen 325 + oxycodone 5 + diclofenac suppository (100 mg). Group 2 : Diclofenac suppository (100 mg) + placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ASA \leq II, Consent to participate in the study, Kidney stones between 4 and 20 mm, No history of previous open surgery, No history of previous crusher. Exclusion criteria: Increased serum creatinine (more than 2 mg/dL), Urinary tract infection, High grade hydronephrosis, Diabetic, Taking NSAIDs, acetaminophen and acetaminophen codeine in the previous 24 hours History of peptic ulcer, Taking peptic ulcer pills, G6PD deficiency, History of liver and kidney disease, History of drug allergy, drug addiction.

Intervention groups

Intervention group 1: Acetaminophen 325 + oxycodone 5 + diclofenac suppository (100 mg) . Intervention group 2: Diclofenac suppository (100 mg) + placebo.

Main outcome variables

Pain control, Complications, hospitalization time, surgical time, and success rate of complete stone therapy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190624043991N18**

Registration date: **2022-09-28, 1401/07/06**

Registration timing: **prospective**

Last update: **2022-09-28, 1401/07/06**

Update count: **0**

Registration date

2022-09-28, 1401/07/06

Registrant information

Name

Seyed Mohammad Kazem Aghamir

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6634 8560

Email address

mkaghamir@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-11, 1401/08/20

Expected recruitment end date

2023-10-12, 1402/07/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the analgesic effect of oral administration of Acetaminophen + Oxycodone after extracorporeal

shock with shock waves

Public title

Evaluation of the analgesic effect after extracorporeal shock with shock waves

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ASA≤II Consent to participate in the study Kidney stones between 4 and 20 mm No history of previous open surgery No history of previous crusher

Exclusion criteria:

Increased serum creatinine (more than 2 mg/dL) Urinary tract infection High grade hydronephrosis Diabetic Taking NSAIDs, acetaminophen and acetaminophen codeine in the previous 24 hours History of peptic ulcer Taking peptic ulcer pills G6PD deficiency History of liver and kidney disease History of drug allergy drug addiction

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

The present study is a Single blind randomized clinical trial. For randomization, the balanced block randomization method with blocks of size 4 is used. Intervention group A and control group B have been determined. After the methodologist prepares the randomization sequence using the sealdenvelop online site, the generated sequence will be made available to a technician outside the research team. Quadruple blocks (A or B) are placed inside the 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. The patient is placed in (acetaminophen 325 + oxycodone 5 + diclofenac suppository (100 mg)) or (placebo + diclofenac suppository (100 mg))group based on the randomly selected envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients who have expressed their consent to participate in the study after surgery without knowing the existence of two drug groups based on a randomly selected envelope are placed in the treatment group (acetaminophen 325 + oxycodone 5 + diclofenac suppository (100 mg)) or Placebo + diclofenac suppository (100 mg).

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee for Research in Tehran University of Medical Sciences

Street address

Room 604, Sixth Floor, medical University Tehran, Central Staff Building, Keshavarz Blvd., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-05-30, 1401/03/09

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.191

Health conditions studied

1

Description of health condition studied

Urethral stone

ICD-10 code

N21

ICD-10 code description

Calculus of lower urinary tract

Primary outcomes

1

Description

Pain control

Timepoint

Immediately, half an hour and a week after extracorporeal shock with shock waves

Method of measurement

Visual analogue scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Acetaminophen 325 + oxycodone 5 + diclofenac suppository (100 mg)

Category

Treatment - Drugs

2**Description**

Intervention group: Diclofenac suppository (100 mg) + placebo

Category

Treatment - Drugs

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, Imam Khomeini 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

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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**Contact****Name of organization / entity**

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Full name of responsible person

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Specialist

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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

Researchers working in academia, physicians, surgeons and hospitals

Under which criteria data/document could be used

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

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

-

Person responsible for updating data**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

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