

# 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)

##### Phone

+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 sealdvelop 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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mkaghamir@tums.ac.ir

**Web page address**

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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, medical University Tehran, Central Staff Building, Keshavarz Blvd., Tehran, Iran

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vcr@tums.ac.ir

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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**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Kazem Aghamir

**Position**

Head of Urology Research Center

**Latest degree**

Specialist

**Other areas of specialty/work**

Urology

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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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