

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigating the effect of prescribing diuretics and the inclined position with the head down for the removal of lower calices stones during extracorporeal shock wave lithotripsy in patients who referred to the Stone Crushing Center

#### Protocol summary

##### Study aim

Investigating the effect of simultaneous administration of diuretics and Head Down for the removal of lower calices stones during Extracorporeal shock wave lithotripsy (ESWL)

##### Design

Equal division of 148 patients into 2 intervention and control groups and permuted block randomization to balance the number of allocated samples.

##### Settings and conduct

Receiving 10 mg of Lasix 30 min before ESWL and 1 lit of IV hydration of 0.9% NaCl during the procedure and 20 to 30 degree angulation of the patient to facilitate the removal of stones from the lower calyx to the pelvis and to investigate the simultaneous effect of diuretics and head down to increase SFR during ESWL at Sina Hospital.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: 1)Age 18 to 60 years 2)lower calyx stones Exclusion criteria: 1)urinary system's anatomical abnormalities 2)Uncorrected coagulation problem 3)Untreated urinary infection or urosepsis 4)Previous urological surgery 5)Obstruction of the urinary tract distal to the stone 6)Unilateral and simultaneous kidney and ureter stones 7)renal failure 8)Suffering from a heart disease such as having a pacemaker 9)tumor in areas exposed to shock 10)Aneurysms 11)Body mass index>40 kg/m<sup>2</sup> 12)Skeletal problems 13)sensitivity to diuretics 14)Pregnancy 15)single kidney. 16)hypotention 17)uncontrolled hypertention 18)central nervous system diseases. 19) history of increased intracranial pressure

##### Intervention groups

Receiving 10 mg of Lasix 30 minutes before ESWL and 1 lit of IV hydration of 0.9% NaCl during the procedure and 20 to 30 degree angulation of the patient to facilitate stone removal from the lower calyx to the pelvis in the intervention group and not receiving these items in the

group the witness

##### Main outcome variables

Pain, nausea, hematuria, urinary tract infection, urethral obstruction, dysuria, metabolic disorders headache, dizziness, blurred vision, BP changes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230214057416N1**

Registration date: **2023-05-02, 1402/02/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-05-02, 1402/02/12**

Update count: **0**

##### Registration date

2023-05-02, 1402/02/12

##### Registrant information

##### Name

Darya Rezaei

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 3307 7658

##### Email address

drrezaei98@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-04-16, 1402/01/27

**Expected recruitment end date**

2024-08-17, 1403/05/27

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of prescribing diuretics and the inclined position with the head down for the removal of lower calices stones during extracorporeal shock wave lithotripsy in patients who referred to the Stone Crushing Center

**Public title**

Investigating the effect of prescribing diuretics and the inclined position with the head down for the removal of lower calices stones during extracorporeal shock wave lithotripsy

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age 18 to 60 years Patients diagnosed with lower calyx stones

**Exclusion criteria:**

anatomical abnormality in urinary system Uncorrected coagulation problem Untreated urinary tract infection or urosepsis Previous urological surgery Obstruction of the urinary tract distal to the stone Unilateral and simultaneous kidney and ureter stones Kidney failure (urine creatinine more than 1.8) Having a cardiovascular disease such as having a pacemaker tumore in areas exposed to shock Aneurysms BMI>40 Kg/m2 Skeletal problems such as inability to take certain positions History of having allergy diuretics pregnancy single kidney hypotention uncontrolled HTN history of CNS disease history of brain tumors history of ICP rise

**Age**

From 18 years old to 60 years old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: 148

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

. We use the permuted block randomization method to balance the number of detected samples. For this purpose, we use the site <https://www.sealedenvelope.com/simple-randomiser/v1/lists> for block randomization and get the following results: Your list Seed: 5000000000000000000 Block sizes: 4 Actual list length: 52 block identifier, block size, sequence within block, treatment • 1, 4, 1, Group A • 1, 4, 2, Group B • 1, 4, 3, Group B • 1, 4, 4, Group A • 2, 4,

1, Group A • 2, 4, 2, Group A • 2, 4, 3, Group B • 2, 4, 4, Group B • 3, 4, 1, Group B • 3, 4, 2, Group A • 3, 4, 3, Group A • 3, 4, 4, Group B • 4, 4, 1, Group A • 4, 4, 2, Group B • 4, 4, 3, Group B • 4, 4, 4, Group A • 5, 4, 1, Group B • 5, 4, 2, Group A • 5, 4, 3, Group B • 5, 4, 4, Group A • 6, 4, 1, Group A • 6, 4, 2, Group A • 6, 4, 3, Group B • 6, 4, 4, Group B • 7, 4, 1, Group A • 7, 4, 2, Group B • 7, 4, 3, Group A • 7, 4, 4, Group B • 8, 4, 1, Group A • 8, 4, 2, Group B • 8, 4, 3, Group A • 8, 4, 4, Group B • 9, 4, 1, Group A • 9, 4, 2, Group B • 9, 4, 3, Group A • 9, 4, 4, Group B • 10, 4, 1, Group B • 10, 4, 2, Group B • 10, 4, 3, Group A • 10, 4, 4, Group A • 11, 4, 1, Group A • 11, 4, 2, Group A • 11, 4, 3, Group B • 11, 4, 4, Group B • 12, 4, 1, Group A • 12, 4, 2, Group B • 12, 4, 3, Group A • 12, 4, 4, Group B • 13, 4, 1, Group B • 13, 4, 2, Group B • 13, 4, 3, Group A • 13, 4, 4, Group A And then we can use coin toss to choose between A and B. Also, a questionnaire has been designed to record information, which includes three parts before the operation, during the operation and after the operation, which are included in the appendices.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Factorial

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Sina Hospital

**Street address**

Tehran - Imam Khomeini St. - Hassan Abad Square - Sina Hospital

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Approval date**

2023-04-15, 1402/01/26

**Ethics committee reference number**

IR.TUMS.SINAHOSPITAL.REC.1402.008

**Health conditions studied****1****Description of health condition studied**

lower calices stones

**ICD-10 code**

## ICD-10 code description

## Primary outcomes

### 1

#### Description

Removal of lower calices stones

#### Timepoint

After two weeks of ESWL

#### Method of measurement

questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: prescribing diuretics and the inclined position with the head down

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Injection of normal saline without diuretics and without head down position

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sina hospital

##### Full name of responsible person

Darya Rezaei

##### Street address

Imam Khomeini St. - Hassan Abad Square

##### City

Tehran

##### Province

Tehran

##### Postal code

1136746911

##### Phone

+98 21 6634 8560

##### Fax

+98 21 6634 8587

##### Email

hosp\_sina@sina.tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Darya Rezaei

##### Street address

Tehran , enghelab square , 16 azar avenue , tehran university of medical science

##### City

Tehran

##### Province

Tehran

##### Postal code

1461884513

##### Phone

+98 21 6443 2592

##### Fax

+98 21 6640 9641

##### Email

publicrel@ut.ac.ir

#### 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

Darya Rezaei

##### Position

medical student

##### Latest degree

Medical doctor

##### Other areas of specialty/work

General Practitioner

##### Street address

16 Azar

##### City

Tehran

##### Province

Tehran

##### Postal code

1461884513

##### Phone

+98 21 6640 5357

**Email**

drrezaei98@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Darya Rezaei

**Position**

medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

16 azar

**City**

Tehran

**Province**

Tehran

**Postal code**

1461884513

**Phone**

+98 21 6640 5357

**Email**

drrezaei98@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Darya Rezaei

**Position**

medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Practitioner

**Street address**

16 azar aven.

**City**

Tehran

**Province**

Tehran

**Postal code**

1461884513

**Phone**

+98 21 6640 5357

**Fax**

**Email**

drrezaei98@gmail.com

## 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**

Undecided - It is not yet known if there will be 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**

Undecided - It is not yet known if there will be 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**

All information except personal information can be shared.

**When the data will become available and for how long**

since 1403

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

All people who need the results of this research, including doctors, researchers, students of medical sciences, etc.

**From where data/document is obtainable**

The Researcher ( Darya Rezaei ) drrezaei98@gmail.com

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

Sending an email and replying to her/him at least 1 week later

**Comments**