Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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/m2 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)
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+98 21 3307 7658
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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: 500000000000000000 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
۱۱۳۶۷۴۶۹۱۱
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
۱۱۳۶۷۴۶۹۱۱
Phone
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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 sciense
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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
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Position

medical student

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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

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1461884513

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+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