

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of isosorbide dinitrate on the duration of kidney stone free after Extra Corporeal Shock Wave Lithotripsy

Protocol summary

Study aim

Determining the effect of isosorbide dinitrate on the duration of excretion of kidney stones after Extra Corporeal Shock Wave Lithotripsy

Design

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial in 178 patients. Lottery was used for randomization.

Settings and conduct

176 patients with stones smaller than 20 mm in the pelvic area, referred to the Extracorporeal Shock Wave Lithotripsy department of Rafsanjan Moradi Hospital during 2024 will be examined. After stone breaking, the patients were randomly divided into two intervention groups (taking 20 mg isosorbide tablets every 12 hours for 2 weeks) and the control group (placebo, an ineffective substance in the form of a tablet that is similar in shape and taste to isosorbide tablets and one of the pharmacists will be prepared) will be placed for 2 weeks.

Participants/Inclusion and exclusion criteria

Weight under 100 kg, stone size up to 20 mm, no history of kidney failure, no history of stone breaking, no history of kidney surgery, no history of stone removal, no history of taking diuretic drugs, no history of taking smooth muscle relaxant drugs, and no history of moderate or severe hydronephrosis.

Intervention groups

The intervention group used 20 mg isosorbide tablets every 12 hours for 2 weeks

Main outcome variables

Stone free

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150317021497N9**

Registration date: **2023-12-20, 1402/09/29**

Registration timing: **prospective**

Last update: **2023-12-20, 1402/09/29**

Update count: **0**

Registration date

2023-12-20, 1402/09/29

Registrant information

Name

Mohammadreza Mokhtaree

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34260081

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mrmokhtaree@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of isosorbide dinitrate on the duration of kidney stone free after Extra Corporeal Shock Wave Lithotripsy

Public title

The effect of isosorbide on the duration of Renal stone free

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent to participate in the study weight under 100 kg stone size up to 20 mm
Exclusion criteria:
Moderate and severe hydronephrosis History of taking smooth muscle relaxant drugs History of taking smooth muscle relaxant drugs History of stone removal History of kidney surgery history of Extra Corporeal Shock Wave Lithotripsy History of renal failure

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **176**

Randomization (investigator's opinion)
Randomized

Randomization description
Random method and after maximum effort for matching based on age, sex, weight and size of the stone

Blinding (investigator's opinion)
Single blinded

Blinding description
The data analyst did not know about the grouping

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rafsanjan University of Medical Sciences

Street address

Imam Ali Blvd.-Central Organization-Building No. 3, Research and Technology Vice-Chancellor

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2019-02-02, 1397/11/13

Ethics committee reference number

IR.RUMS.REC.1397.200

Health conditions studied

1

Description of health condition studied

Calculus of kidney

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

Duration of stone free

Timepoint

After prescribing the drug

Method of measurement

check list

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Administration of isosorbide

Category

Treatment - Drugs

2

Description

Control group: Placebo administration

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Moradi Hospital, Rafsanjan University of Medical Sciences

Full name of responsible person

Alireza Nazari

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Moradi hospital, Shohada ST

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Rafsanjan 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
Rafsanjan University of Medical Sciences
Full name of responsible person
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Vice Chancellery for Research & Technology
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Web page address

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

The data will be available only to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

To receive the data, a valid letter from the highest authority of the person's university is required. Any analysis on the data will be done with the knowledge and permission of the researchers.

From where data/document is obtainable

Vice Chancellery for Research & Technology of Rafsanjan University of Medical Sciences

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

After submitting the request to the Research and Technology Vice-Chancellor of Rafsanjan University of Medical Sciences, the review process will begin. After reviewing the application and approval, the data will be provided to the applicant.

Comments