Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

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

Protocol summary

Study aim
Determining the effect of isosorbide dinitrate on the duration of excretion of kidney stones after Extra Corporeal Shock Wake 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 Wake 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
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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 Wake 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 Wake 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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Sponsors / Funding sources

1

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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
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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