

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of hydrochlorothiazide at stone free time after extra corporeal shock wave lithotripsy on patients referred to ESWL ward of Moradi hospital of Rafsanjan

Protocol summary

Study aim

Study of the Effect of Hydrochlorothiazide on the Duration of Stone free after Extra corporal shock wave lithotripsy

Design

In this research, 276 eligible patients with Upper ureter stone referring to Moradi hospital were chosen purposefully. Then, patients were randomly divided into two control and intervention groups and a code was allocated to each one of them.

Settings and conduct

Patients in the intervention group, after ESWL, receive 25 mg of hydrochlorothiazide tablets every 12 hours for two weeks. The control group received vitamin B1 tablets every 12 hours for two weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Upper ureter stones under 20 mm
Exclusion criteria: Renal diseases, history of surgery, No Informed consent

Intervention groups

Patients in the intervention group, after ESWL, receive 25 mg of hydrochlorothiazide tablets twice a day for two weeks. The control group received vitamin B1 tablets for two weeks.

Main outcome variables

Stone free duration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171104037212N2**
Registration date: **2018-01-24, 1396/11/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-24, 1396/11/04**

Update count: **0**

Registration date

2018-01-24, 1396/11/04

Registrant information

Name

Alireza Nazari

Name of organization / entity

Rafsanjan University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3426 0080

Email address

dr.nazari@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Rafsanjan University of medical sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-11-22, 1397/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of hydrochlorothiazide at stone free time after extra corporeal shock wave lithotripsy on patients referred to ESWL ward of Moradi hospital of Rafsanjan

Public title

Efficacy of hydrochlorothiazide at renal pelvis stone free time after extra corporeal shock wave lithotripsy (ESWL)

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Renal pelvic stone Stone size equal or below 20 millimeters

Exclusion criteria:

Renal failure History of Extracorporeal shock wave lithotripsy History of renal surgery History of stone passage History of using Diuretic drugs History of using smooth muscle relaxant drugs Patients with moderate or severe hydronephrosis

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: 278

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, radiologist, nurse do not know how to grouping.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics in medical researchs

Street address

Shohada

City

Rafsanjan

Province

Kerman

Postal code

7713961151

Approval date

2015-08-23, 1394/06/01

Ethics committee reference number

IR.RUMS.REC.1394.176

Health conditions studied

1

Description of health condition studied

Stone in kidney

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

The duration, the number of days from the time of the Extracorporeal shock wave lithotripsy to the time of last stone fragment passage

Timepoint

Day after Extracorporeal shock wave lithotripsy

Method of measurement

Check list

Secondary outcomes

1

Description

Stone free

Timepoint

daily

Method of measurement

Check list

Intervention groups

1

Description

Intervention group: Hydrochlorothiazide Tablet administration 25 mg, every 12 hours for two weeks

Category

Treatment - Drugs

2

Description

Control group: Tablet Vitamin B1 administration 150mg, every 12 hours for two weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Moradi hospital
Full name of responsible person
Alireza Nazari
Street address
Shohada
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Postal code
7713961151
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Email
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Full name of responsible person
Mohammadreza Mokhtaree
Position
education expert
Latest degree
Master
Other areas of specialty/work
Psychology
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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rafsanjan University of Medical Sciences
Full name of responsible person
Ali Shamsizadeh, PhD
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alishamsy@gmail.com

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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rafsanjan University of medical sciences
Full name of responsible person
Alireza Nazari
Position
Urology specialist
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Non-approval of the Ethics Committee

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Checklists are available

When the data will become available and for how long

2018

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Academic member

From where data/document is obtainable

mrmokhtaree@yahoo.com

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

Agreement of the researchers, agreement of the authorities of the organization

Comments