

# 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  
**City**  
Rafsanjan  
**Province**  
Kerman  
**Postal code**  
7713961151  
**Phone**  
+98 34 3426 0080  
**Email**  
dr.nazari@rums.ac.ir

**Full name of responsible person**  
Mohammadreza Mokhtaree  
**Position**  
education expert  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Psychology  
**Street address**  
Education unit, Moradi hospital, Shohada ST  
**City**  
Rafsanjan  
**Province**  
Kerman  
**Postal code**  
7713961151  
**Phone**  
+98 34 3426 0080  
**Fax**  
**Email**  
mrmokhtaree@rums.ac.ir  
**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  
**Street address**  
Imam Ali, Blvd  
**City**  
Rafsanjan  
**Province**  
Kerman  
**Postal code**  
7713961151  
**Phone**  
+98 34 3428 0038  
**Email**  
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**  
Urology  
**Street address**  
Moradi hospital, Shohada Street  
**City**  
Rafsanjan  
**Province**  
Kerman  
**Postal code**  
7713961151  
**Phone**  
+98 34 3426 0080  
**Fax**  
**Email**  
dr.nazari@rums.ac.ir  
**Web page address**

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Rafsanjan University of Medical Sciences  
**Full name of responsible person**  
Mohammadreza Mokhtaree  
**Position**  
clinical education staff  
**Latest degree**

Master

**Other areas of specialty/work**

Psychology

**Street address**

Shohada

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7713961151

**Phone**

+98 983434260080

**Fax**

**Email**

mrmokhtaree@rums.ac.ir

**Web page address**

**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**