

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of the effect of Rudioretic supplement comparing to placebo on renal stone: A randomized clinical trial

#### Protocol summary

##### Study aim

Determining the effect of Rudioretic supplement on kidney stone expulsion

##### Design

160 participants (no=40 per group) are randomly assigned to 2 intervention groups (A- capsule, B- drops) and 2 placebo groups (C- capsule, D- drop) using a random digit table. Study phase 3.

##### Settings and conduct

This randomized controlled trial will be performed in Fayaz Bakhsh hospital. Inclusion criteria will be checked by a sonographer. Included patients will randomly be assigned to supplement and placebo groups. In the end, sonography will be repeated. Before and after 6 weeks of intervention urine biochemical test, 24h urine volume and urine pH will be determined. At last, the rate of stone expulsion will compare in two groups with SPSS 22 software.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age>18, having kidney stone without hydronephrosis, No need for medication. Exclusion criteria: Pregnancy, lactation, Receiving drugs that affect kidney stones.

##### Intervention groups

Patients in intervention group (A) will receive 2 capsules (500 mg) of Rudioretic every 8 hours with empty stomach. Intervention group (B) will consume 40 drops of Rudioretic every 8 hours. Placebo group (C) will receive placebo capsule every 8 hours and placebo group (D) will receive 40 drops of placebo every 8 hours. Rudioretic capsule and drop contain similar amount of Zea mays, Apium graveolens, Equisetum arvense and Urtica dioica L. Placebo capsules and drop contain maltodextrin. All groups receive supplement or placebo for 6 weeks

##### Main outcome variables

Excreted kidney stone number

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20140804018677N12**

Registration date: **2021-08-17, 1400/05/26**

Registration timing: **prospective**

Last update: **2021-08-17, 1400/05/26**

Update count: **0**

##### Registration date

2021-08-17, 1400/05/26

##### Registrant information

##### Name

soodeh razeghi Jahromi

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6634 8500

##### Email address

razeghi@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-09-11, 1400/06/20

##### Expected recruitment end date

2022-02-09, 1400/11/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of the effect of Rudioretic supplement comparing to placebo on renal stone: A randomized clinical trial

## Public title

Rudioretic supplement and kidney stone

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Diagnosed with a kidney stone without hydronephrosis and no need for medication Age between 18-45 years Willing to participate in the study

### Exclusion criteria:

Pregnancy or lactation Having known heart disease Receiving drugs that affect kidney stones

## Age

From **18 years** old to **45 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **160**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The Block Randomization method is used to randomize the patients. For randomization, we will visit [www.sealedenvelope.com](http://www.sealedenvelope.com) and use the randomization tab to make a list considering the number of intervention groups, sample size, block size. Block size will be 8 (AABBCCDD and other compositions). The prepared list that contains the pattern of patient allocation will be obtained and used. This site is designed in such a way that there is no limit on the number of groups for random allocation. According to the total number of samples required for the study, which is 160 patients: 40 patients in the intervention group with capsule (A), 40 patients in the intervention group with drop (B), 40 patients in the control group with capsule (C), and patients in the control group with drop. blocks will be randomly Then 160 pockets (40 pockets containing paper containing A, 40 containing B, 40 pockets containing C, and 40 pockets containing D) will be prepared based on sample size. According to a list of blocks, a trained person will be set the row of pockets. After the admission of each patient will be given a pocket and assigned to Group A (intervention 1) or B (intervention 2) or C (control group 1) or D (control group 2). The sampling process will be performed sequentially until the end of the completion of the sample size.

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of research and technology deputy of Shahid Beheshti University of Medical Sciences

##### Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

##### City

Tehran

##### Province

Tehran

##### Postal code

1981619573

#### Approval date

2019-02-17, 1397/11/28

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1397.1304

## Health conditions studied

### 1

#### Description of health condition studied

Kidney stone

#### ICD-10 code

N20.0

#### ICD-10 code description

Calculus of kidney

## Primary outcomes

### 1

#### Description

Number of excreted kidney stone

#### Timepoint

Start of intervention and a month later

#### Method of measurement

Ultrasonography and blood and urine tests

### 2

#### Description

Stone size

#### Timepoint

Start of intervention and a month later

#### Method of measurement

Sonography

## Secondary outcomes

## 1

### **Description**

urine volume 24 h

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

Urine 24 h test by BT-1500 autoanalyser

## 2

### **Description**

Creatinine in urine 24h

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

Urine 24h test by Pars Azmoon kit

## 3

### **Description**

oxalate in urine 24 h

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

urine 24 h test by Darmankau kit

## 4

### **Description**

Citrate in urine 24 h

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

urine 24 h test by Darmankau kit

## 5

### **Description**

Uric acid in urine 24 h

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

urine 24h test by Pars Azmoon kit

## 6

### **Description**

Urine specific gravity

### **Timepoint**

Start of intervention and a month later

### **Method of measurement**

Urinalysis by BT-1500 autoanalyser

## **Intervention groups**

### 1

#### **Description**

Supplement group A: will receive 2 capsules of Rudioretic every 8 hours with empty stomach for 6 weeks. Each capsule contain 500 mg of Zea mays, Apium graveolens, Equisetum arvense and Urtica dioica L.

#### **Category**

Treatment - Other

### 2

#### **Description**

Supplement group B: will receive 40 drops of Rudioretic every 8 hours with empty stomach for 6 weeks. Rudioretic contain Zea mays, Apium graveolens, Equisetum arvense and Urtica dioica L.

#### **Category**

Treatment - Other

### 3

#### **Description**

Placebo group C: will receive 2 capsules of placebo contains maltodextrine every 8 hours for 6 weeks .

#### **Category**

Placebo

### 4

#### **Description**

Placebo group D: will receive 40 drops of placebo contains maltodextrine every 8 hours for 6 weeks .

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Fayaz Bakhsh hospital

##### **Full name of responsible person**

Soodeh Razeghi Jahromi

##### **Street address**

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1981619573

##### **Phone**

+98 21 2235 7483

##### **Email**

soodehrazeghi@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Afshin Zarghi

##### **Street address**

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1981619573

**Phone**

+98 21 2235 7483

**Email**

soodehrazeghi@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Soodeh Razghei Jahromi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1981619573

**Phone**

+98 21 2235 7483

**Email**

soodehrazeghi@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Soodeh Razghei Jahromi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1981619573

**Phone**

+98 21 2235 7483

**Email**

soodehrazeghi@gmail.com

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Soodeh Razghei Jahromi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

No. 7, West Arghavan St., Farahzadi Blv., Qods Town

**City**

Tehran

**Province**

Tehran

**Postal code**

1981619573

**Phone**

+98 21 2235 7483

**Email**

soodehrazeghi@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**

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 would be available to public

**When the data will become available and for how long**

Starting 6 months after publication

**To whom data/document is available**

To all

**Under which criteria data/document could be used**

No other criteria

**From where data/document is obtainable**

Email to soodehrazeghi@gmail.com

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

Sending email

**Comments**