

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Evaluation of the effectiveness of oral solution containing five herbal extracts compared to placebo in the reduction of size and number of stones in patients with urolithiasis

#### Protocol summary

##### Study aim

Evaluating effect of the oral solution with five herbal extracts in the treatment of urolithiasis

##### Design

Two arm parallel group randomized double-blind placebo-controlled clinical trial with sample size of 58 patients in each group with simple randomization method

##### Settings and conduct

Patients are selected from those referred to the clinic of Al-Zahra Hospital. Participants are randomly assigned to either drug or placebo groups. Prior to intervention, patients in both groups will be sampled for a 24-hour urine sample and urine volume, calcium, sodium, citrate, oxalate, urea, creatinine, uric acid and cystine and urine pH will be determined. The number and size of stones will be determined per patient. For drug group, the herbal solution will be administered at 60 drops thrice daily, and for the placebo group, the placebo solution will be given for 4 weeks. The changes of mentioned variables as well as complete expulsion of stone will be evaluated at the end of intervention. The patients and prescribing physician will be blind to the type of intervention; because, drug and placebo solutions will be prepared in similar bottles by the pharmaceutical company.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18; symptomatic or asymptomatic urinary tract stones; Stone size of 10 mm or less. Exclusion criteria: having malignancy with bone metastasis, hyperthyroidism, hyperparathyroidism, psychosis, renal dysfunction, gout or hyperuricemia; use of other traditional products and complementary medicine used in the treatment of urolithiasis from one week before the intervention

##### Intervention groups

Intervention group: herbal solution, 60 drops 3 times

daily concurrent with standard treatment Control group: placebo solution 60 drops 3 times daily concurrent with standard treatment

##### Main outcome variables

stone size, number of people with complete stone expulsion

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150721023282N4**

Registration date: **2019-12-01, 1398/09/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-12-01, 1398/09/10**

Update count: **0**

##### Registration date

2019-12-01, 1398/09/10

##### Registrant information

##### Name

Rasool Soltani

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3792 7067

##### Email address

soltani@pharm.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-09-22, 1398/06/31

**Expected recruitment end date**

2020-03-20, 1399/01/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effectiveness of oral solution containing five herbal extracts compared to placebo in the reduction of size and number of stones in patients with urolithiasis

**Public title**

Evaluation of the effect of the oral solution including six herbal extracts in the treatment of urolithiasis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Symptomatic or asymptomatic urinary tract stones Stone size of 10 mm or less

**Exclusion criteria:**

Structural disorder of the urinary tract or urinary tract infection

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **116**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple Randomization Individual Random Number Table Even Numbers: Drug Group; Odd Numbers: Control Group

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients, the prescribing physician and the data analyst will be blind to the intervention type. The drug and placebo solutions will be prepared in similar coded bottles and given to the chief researcher. A bottle will be given to each patient according to the chief researcher.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethical Committee of Isfahan University of Medical Sciences

**Street address**

Isfahan University of Medical Sciences, Hezar-Jerib Ave.

**City**

isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2019-05-31, 1398/03/10

**Ethics committee reference number**

IR.MUI.RESEARCH.REC.1398.383

**Health conditions studied****1****Description of health condition studied**

urolithiasis

**ICD-10 code**

N20

**ICD-10 code description**

Calculus of kidney and ureter

**Primary outcomes****1****Description**

Change of the size of the stone

**Timepoint**

Before and after the end of intervention

**Method of measurement**

Ultrasonography

**2****Description**

Percentage of patients with complete stone expulsion

**Timepoint**

Before and after the end of intervention

**Method of measurement**

Ultrasonography

**Secondary outcomes**

empty

## Intervention groups

1

### Description

Intervention group: Herbal drops 60 drops three times daily for 8 weeks

### Category

Treatment - Drugs

2

### Description

Control group: Placebo solution 60 drops three times daily for 8 weeks

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Al-Zahra Hospital

#### Full name of responsible person

Rasool Soltani

#### Street address

Soffeh Ave.

#### City

Esfahan

#### Province

Isfahan

#### Postal code

8174675731

#### Phone

+98 31 3620 2020

#### Email

soltani@pharm.mui.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Esfahan University of Medical Sciences

#### Full name of responsible person

Shaghayegh Haghjooy Javanmard

#### Street address

Hezar-Jerib Ave.

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81746-83461

#### Phone

+98 31 3668 0048

#### Email

soltani@pharm.mui.ac.ir

#### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

#### Full name of responsible person

Rasool Soltani

#### Position

Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Medical Pharmacy

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No. 20, Bagh Daryacheh Ave.

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## Person responsible for scientific inquiries

### Contact

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Esfahan University of Medical Sciences

#### Full name of responsible person

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**Person responsible for updating data****Contact****Name of organization / entity**

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Medical Pharmacy

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**City****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**

More data is not present.

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available