

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Library study of kidney stone dissolving medicaments in Persian medicine and evaluation of a related multi-ingredient formulation in dissolving calcium kidneystones; a double-blind randomized clinical trial

#### Protocol summary

##### Study aim

Preparation of new herbal formulations for kidney stones

##### Design

Sixty patients will be divided into two groups of 30, one group will receive medication for 6 weeks and the control group will receive a placebo. At the beginning and end of the study, the results of the analysis of urine and blood samples and imaging will be examined.

##### Settings and conduct

The study is done in Motahhari and Imam Reza clinics affiliated to Shiraz University of Medical Sciences. After examining the patient and confirming the conditions for admission to the study and obtaining informed consent, the doctor will provide the patient with a medicine or placebo.

##### Participants/Inclusion and exclusion criteria

Age 18 years and older  
5 mm calcium kidney stones in the lower lobe  
Willingness to participate in the study  
No pregnancy and lactation  
Lack of acute and chronic renal failure

##### Intervention groups

30 patients in intervention group consume 2 capsules of freeze dried water extract of 6 plants daily. 30 patients in control group consumes 2 capsules of wheat flour as placebo daily.

##### Main outcome variables

kidney function test, liver function test, Ca and P serum levels, urine analysis, 24 h urine volume and stone diameter

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20191212045709N1**

Registration date: **2020-09-29, 1399/07/08**

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

Last update: **2020-09-29, 1399/07/08**

Update count: **0**

##### Registration date

2020-09-29, 1399/07/08

##### Registrant information

###### Name

Ramin Ansari

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3242 4255

###### Email address

ansariramin94@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-15, 1398/10/25

##### Expected recruitment end date

2020-11-21, 1399/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Library study of kidney stone dissolving medicaments in Persian medicine and evaluation of a related multi-ingredient formulation in dissolving calcium kidneystones; a double-blind randomized clinical trial

##### Public title

Library study of kidney stone dissolving medicaments in Persian medicine and evaluation of a related multi-ingredient formulation in dissolving calcium kidneystones; a double-blind randomized clinical trial

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Age 18 years and older Calcium kidney stones with a size of 5 mm or more based on imaging results Lack of confirmed history of acute renal failure Lack of confirmed history of chronic kidney disease having no present urinary tract infection no concurrent use of medications including:®Sankol, ®Rowatinex and Cystone® no pregnancy or breast feeding

##### **Exclusion criteria:**

Age 18 years and older Calcium kidney stones with a size of 5 mm or more based on imaging results Lack of confirmed history of acute renal failure Lack of confirmed history of chronic kidney disease having no present urinary tract infection no concurrent use of medications including:®Sankol, ®Rowatinex and Cystone® no pregnancy or breast feeding

#### **Age**

From **18 years** old to **65 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

- Participant
- Care provider
- Investigator

#### **Sample size**

Target sample size: **60**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

A total of 60 patients were randomly divided in to two groups of 30 each in a randomized double-blind placebo-controlled design using permuted block randomization method. The sample size and randomization were done by a computer- generated statistical program. Minimum sample size for each group was 13 patients. All patients received either 2 capsules of drug or identical-looking placebos at a dose of 2 capsules once daily for a period of 6 weeks.

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

The study will be a double blind trial and only the evaluator knows the results and the code of the drug or placebo group.The capsules of the drug group and the placebo are quite similar in appearance.The drug and placebo groups will be separated by receiving a code.

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

##### **Street address**

anvari str- zand blvd- shiraz

##### **City**

shiraz

##### **Province**

Fars

##### **Postal code**

7139745197

#### **Approval date**

2019-11-06, 1398/08/15

#### **Ethics committee reference number**

IR.SUMS.REC.1398.924

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

renal stone

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### **1**

#### **Description**

liver function test- renal function test-Ca and P serum level, urine analysis, 24 hour urine volume and stone diameter

#### **Timepoint**

At the beginning of the study and one month after the end of the course of medication

#### **Method of measurement**

KUB- URINE ANALYSIS-BLOOD ANALYSIS

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

The intervention group consumes 2 capsules (one in the morning and one at night) of freeze dried water extract of 6 plants including: Tribulus terrestris-Foeniculum vulgare-Pimpinella anisum- Cucumis sativus-Cucurbita pepo-Apium graveolens. the control group consumes 2

capsules of wheat flour as placebo daily. Blood sample and 24 hours urine of patients will analyzed at the beginning and end of the study and the imaging will be done for analyzing the size and number of stones.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

SHAHID MOTAHARI CLINIC

**Full name of responsible person**

MOHAMMAD MEHDI ZARSHENAS

**Street address**

NAMAZI SQUIRE- SHIRAZ

**City**

SHIRAZ

**Province**

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NEMAZEE-INF@SUMS.AC.IR

**Web page address**

<https://namazi.sums.ac.ir/page-Namazi/fa/65/form/pld5524>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

دانشگاه علوم پزشکی شیراز

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**Web page address**

<https://sums.ac.ir/page-Main/fa/0/form/pld656>

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor**

**organization/entity?**

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

MM ZARSHENAS

**Position**

ASSISTANT PROFESSOR

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

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<https://pharmacy.sums.ac.ir/page-pharmacy/fa/79/form/pld10611>

## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Web page address**

<https://pharmacy.sums.ac.ir/page-pharmacy/fa/79/form/pld10611>

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**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**

Undecided - It is not yet known if there will be 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**

JUST THE RESULTS WILL BE PUBLISHED

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

AT THE END OF THE STUDY

**To whom data/document is available**

UNIVERSITIES

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

SCIENTIFIC RESEARCH

**From where data/document is obtainable**

ZARM@SUMS.AC.IR

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

CONTACT ZARM@SUMS.AC.IR

**Comments**