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

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Iran (Islamic Republic of)

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+98 71 3242 4255

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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 analized at the beginning and end of the study and the imaging will be done for analizing 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

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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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https://sums.ac.ir/page-Main/fa/0/form/pId656

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
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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