Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Safety and efficacy of a polyherbal formulation in patients with calcium renal stones: A randomized, clinical trial

Protocol summary

Study aim
Evaluatinf the safety and efficacy of a polyherbal formulation in patients with calcium renal stones

Design
Controlled clinical trial, with parallel groups, triple-blind, randomized, phase 3 on 50 patients

Settings and conduct
Eligible participants who refer to the Urology Clinic of Imam Ali Hospital or a designated private clinic in May - October 2025 will be enrolled in the study. The diagnosis of kidney stones is confirmed using KUB ultrasound or spiral computed tomography scan without contrast. Composition analysis is used to determine the type of stone. Patients are randomly assigned to two groups (placebo and drug). Block randomization (block number 4) is used to randomize patients. Both groups are allowed to use analgesics (ketorolac) and muscle relaxants (hyoscine) on a PRN basis if necessary. In addition to analgesics, the drug group will receive 10 grams of the concoction daily (divided into two doses of 5 grams, 15 minutes after lunch and dinner) for 6 days. All patients will be clinically examined at baseline and after 10 days. Ultrasound, urinalysis, and hematological and biochemical parameters will be checked at baseline and 10 days after the start of treatment.

Participants/Inclusion and exclusion criteria
included criteria: aged 18 to 60 years with kidney stones 5 mm or larger in the lower pole of the kidney Exclusion criteria include severe urinary tract infection, acute kidney injury, CKD, diabetes, concomitant use of herbal remedies for dissolving kidney stones such as Sankol®, and pregnant or lactating women, patients with coagulation problems or taking anticoagulant medications, and individuals with a history of erosions in the gastrointestinal tract.

Intervention groups
1. Drug group: A combination of medicinal plant powders including black cumin, black cumin, ginger, and pepper mixed in a specific ratio in honey 2. Placebo group

Main outcome variables
stone size

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180923041093N8**
Registration date: **2026-05-08, 1405/02/18**
Registration timing: **prospective**

Last update: **2026-05-08, 1405/02/18**
Update count: **0**

Registration date
2026-05-08, 1405/02/18

Registrant information

Name
Fatemeh sadat Hasheminasab

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 5333 8547

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-05-22, 1405/03/01

Expected recruitment end date
2026-11-21, 1405/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Safety and efficacy of a polyherbal formulation in patients with calcium renal stones: A randomized, clinical trial

Public title
Herbal medicine in renal stone

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Kidney stones 5 mm or larger in the lower pole of the kidney Age between 18 and 60 years old

Exclusion criteria:
severe urinary tract infection acute renal injury CKD diabetes concomitant use of herbal remedies to dissolve kidney stones such as Sankol®, Rowatinex®, Cystone®, Lithorex-B® or Urtica ZardBand® pregnant or lactating women patients with coagulation problems or taking anticoagulant medications a history of ulcers or erosions in the gastrointestinal tract

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
A block randomization method (block number 4) will be used to randomize patients.

Blinding (investigator's opinion)
Triple blinded

Blinding description
To conceal allocation, sealed, numbered, opaque, and sealed envelopes will be used. Each envelope will be labeled with a serial number and delivered to a third party (clinic secretary) who will open the sealed envelope after the patient consents to participate and is assigned to a treatment group.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
کمیته اخلاق در پژوهش دانشگاه علوم پزشکی زاهدان

Street address
Zahedan University of Medical Sciences Campus, Dr. Hesabi Square, Zahedan, Iran

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Postal code
9816743463

Approval date
2026-04-08, 1405/01/19

Ethics committee reference number
IR.ZAUMS.REC.1405.011

Health conditions studied

1

Description of health condition studied
Nephrolithiasis

ICD-10 code
N20.0

ICD-10 code description
Calculus of kidney

Primary outcomes

1

Description
renal stone size

Timepoint
At the baseline (before the intervention) and 10 days after starting the drug

Method of measurement
Ultrasound

Secondary outcomes

1

Description
BUN

Timepoint
At baseline (before the intervention) and 10 days after starting the drug

Method of measurement
blood test

2

Description
Serum creatinine

Timepoint

At baseline (before the intervention) and 10 days after starting the drug

Method of measurement

blood test

3

Description

Serum calcium

Timepoint

At baseline (before the intervention) and 10 days after starting the drug

Method of measurement

blood test

4

Description

Liver enzymes

Timepoint

At baseline (before the intervention) and 10 days after starting the drug

Method of measurement

blood test

5

Description

Urine specific gravity

Timepoint

At baseline (before the intervention) and 10 days after starting the drug

Method of measurement

Urine analysis

6

Description

24 h urine volume

Timepoint

At baseline (before the intervention) and 10 days after starting the drug

Method of measurement

Graduated container

7

Description

24 h urine calcium

Timepoint

At baseline (before the intervention) and 10 days after starting the drug

Method of measurement

Urine analysis

8

Description

24 h urine magnesium

Timepoint

At baseline (before the intervention) and 10 days after starting the drug

Method of measurement

Urine analysis

9

Description

Number of analgesics used

Timepoint

On days 1, 2, 3, 4, and 5 after the start of the intervention

Method of measurement

Asking the patient

Intervention groups

1

Description

Intervention group: IA specific amount of black pepper, black seed, black cumin, and ginger rhizome powder is ground and mixed with honey. The patient consumes 5 grams of this mixture daily after lunch and 5 grams after dinner for 6 days.

Category

Treatment - Drugs

2

Description

Control group: Placebo (one thirtieth of the herbal powder used as intervention drug mixed in honey). The patient takes 5 grams of this mixture daily after lunch and 5 grams after dinner for 6 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Hospital

Full name of responsible person

Behzad Naroui

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2

Recruitment center

Name of recruitment center

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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
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Person responsible for updating data

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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
Not applicable
Title and more details about the data/document
After the study, information about the main outcome will be shared
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
For academic and scientific researchers only
Under which criteria data/document could be used
Only in line with the analysis and research related to the main title of this study
From where data/document is obtainable
Email to hashemifa67@gmail.com
What processes are involved for a request to access data/document
The data will be provided to the applicant within one month after reviewing and confirming the request.
Comments