Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 urolitiasis

Protocol summary

Study aim

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

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 urolitiasis 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

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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 urolitiasis

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
Isfehan
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
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Soffeh Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Person responsible for updating data

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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