Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of safety and efficacy of Lapis judaicus versus hydrochlorothiazide in patients with renal stones: a randomized clinical trial.

Protocol summary

Study aim

1 Determination the effect and safety of oral Lapis judaicus capsules on kidney stone compared to hydrochlorothiazide

Design

Clinical trial with 3 parallel groups, double blind, randomised controlled trial.

Settings and conduct

Patients will be selected from patients that will be referred to shiraz university of medical sciences clinics and this study will be done at Imam Reza Clinic. Only the pharmacist knows the contents of the capsules, and the rest of the people include the researcher, the presenter, the patient, the statistician,....are blind.

Participants/Inclusion and exclusion criteria

Have informed and written consent to participate in the study. Opaque stone greater than or equal to 5 mm and less than or equal to 10 mm. Age of 18 to 65 years of both sexes. Male and female. Satisfaction with the non-use of non-protocol treatments. In one Last month, there was no effective drug on renal stone. Not Pregnancy or lactation. Not sensitization to medications. Not obstruction or other emergency problem during intervention. Not organic disease. Not Kidney transplant or single kidney.

Intervention groups

75 patients with kidney stones will be divided into three groups. First group will receive 2 capsules containing 1 gram of Lapis judaicus powder daily for two months. Second group : 2 capsules containing 12.5 mg hydrochlorothiazide +1 gram of Lapis judaicus powder daily for two months. Third group: 2 capsules containing 12.5 mg hydrochlorothiazide daily for two months.

Main outcome variables

Kidney stone size in sonography

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190413043264N1**
Registration date: **2019-08-18, 1398/05/27**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-18, 1398/05/27**
Update count: **0**

Registration date

2019-08-18, 1398/05/27

Registrant information

Name

Elham Akbarzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3628 4165

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akbarzadeh_e@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-05, 1398/04/14

Expected recruitment end date

2019-09-05, 1398/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of safety and efficacy of Lapis judaicus versus hydrochlorothiazide in patients with renal stones: a randomized clinical trial.

Public title
Investigating the effect and safety of Lapis judaicus on kidney stones

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Have informed and written consent to participate in the study. Opaque stone greater than or equal to 5 mm and less than or equal to 10 mm. Age of 18 to 65 years of both sexes.Male and female. Satisfaction with the non-use of non-protocol treatments In one Last month, there was no effective drug on renal stone.

Exclusion criteria:
Pregnancy or lactation Sensitization to drugs of intervention Sensitization to sulfur Symptoms of digestive, liver or kidney, heart disease · · Obstruction or other emergency problem during intervention Dissatisfaction with the patient to continue the plan for both Organic disease (kidney, liver, heart disease, cancer, diabetes) Smoking, alcohol and substance abuse Coagulopathy disease Kidney transplant or single kidney.

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method is block type alog with using random numbers table. The pharmacist will prepare the three groups of drugs in the same capsule and in the same boxes.The number of boxes is numbered according to the random number and the researcher will randomly give the medicine to patients.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patient, the drug delivery officer, physician and the statistical analyst of the result, will be blind, and only the drug manufacture can decode based on the original from of randomization.

Placebo
Not 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
University of Medical Science, Zand Ave, Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
صندوق پستي71345-1978

Approval date
2019-05-05, 1398/02/15

Ethics committee reference number
IR.SUMS.MED.REC.1397.481

Health conditions studied

1

Description of health condition studied
renal stone

ICD-10 code
XIV

ICD-10 code description
XIV Diseases of the genitourinary system

Primary outcomes

1

Description
Renal stone size

Timepoint
2 Months

Method of measurement
KUB Sonography

Secondary outcomes

1

Description
BUN

Timepoint
Before and after intervention

Method of measurement
DIRUI Automatic Analyzer

2

Description
Cr
Timepoint
Before and after intervention
Method of measurement
DIRUI Automatic Analyzer

3

Description
Calcium
Timepoint
Before and after intervention
Method of measurement
DIRUI Automatic Analyzer

4

Description
Aspartate Aminotransferase (AST)
Timepoint
Before and after intervention
Method of measurement
DIRUI Automatic Analyzer

5

Description
Alanine Aminotransferas(ALT)
Timepoint
Before and after intervention
Method of measurement
DIRUI Automatic Analyzer

6

Description
Urinalysis
Timepoint
Before and after intervention
Method of measurement
refractometry, microscopic and macroscopic urinalysis

7

Description
24- hour urine calcium
Timepoint
Before and after intervention
Method of measurement
DIRUI Automatic Analyzer

8

Description
24- hour urine magnesium
Timepoint
Before and after intervention
Method of measurement
DIRUI Automatic Analyzer

9

Description
24 -Hour urine citrate
Timepoint
Before and after intervention
Method of measurement
DIRUI Automatic Analyzer

Intervention groups

1

Description
Intervention group A:Two capsules containing Lapis judaicus 1 gram for 2 months .
Category
Treatment - Drugs

2

Description
Intervention group B; Two capsules containing Lapis judaicus 1 gram +12.5 mg of hydrochlorothiazide for 2 months.
Category
Treatment - Drugs

3

Description
Control group C: Two capsules containing 12.5 mg of hydrochlorothiazide for 2 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinics of Shiraz University of Medical Sciences
Full name of responsible person
Elham Akbarzadeh
Street address
Emam Reza Clinic, Zand Ave, Namazi Square
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71348714737
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+98 71 3212 7001
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Yoness Ghasemi
Street address
l, Zand Avenue, Shiraz, Iran
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Fars
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7134845794
Phone
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Fax
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Email
drjaladat@gmail.om
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
Elham Akbarzadeh
Position
resident
Latest degree
Specialist
Other areas of specialty/work
Traditional Medicine
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Person responsible for updating data

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akbarzadeh_e@sums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Yes - There is 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

Some of the data, such as clinical examination information, renal stone changes, or lab data results, can be shared.

When the data will become available and for how long

Starting 12 months after publication

To whom data/document is available

People working in academic institutions.

Under which criteria data/document could be used

There is not any decision yet.

From where data/document is obtainable

Contact the main researcher

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

After correspondence with the researcher, within the framework of the declarations and in the shortest possible time.

Comments