

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Etiology and pathogenesis of kidney Stone formation from the Perspective of Persian Medicine and Clinical evaluating of cynodon dactylon and dolichos biflorus extracts on Kidney Stone.

Protocol summary

Study aim

Evaluation of the Effect of Rhizome Extract of Plant and Dactylon Plants on the Removal or Reduction of Kidney Stone Size

Design

96 patients with kidney stones were divided equally and randomly. The method of permutation blocks by software and two unrelated 3 parallel groups of 32 people. Herbal Medicine Group, Herbal Drug Group and Placebo Group The placebo group has the usual recommendations and placebo. Intervention teams will receive herbal medicines for 21 days. Patients are allowed to use commonly used kidney stone therapy. Groups are examined in parallel

Settings and conduct

The study is designed at the Mashhad traditional medicine clinic and will be conducted at the clinic of Imam Reza Hospital in Mashhad

Participants/Inclusion and exclusion criteria

Age of 20 to 60 years Renal stone with ultrasound confirmation Kidney stone larger than 5 mm.Satisfaction with the treatment of traditional medicineExit:Pregnancy for women and breastfeedingHistory of chronic kidney diseaseKidney failureMedium or severe hydronephrosis

Intervention groups

To the intervention group, 2 capsules of 800 mg daily containing the extract of rhizome of the plant And to another group, 2 capsules of 800 milligrams containing the extract of the grapefruit And to the control group, two capsules containing placebo are given daily

Main outcome variables

Kidney stone size The amount of kidney stone displacement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190410043235N1**

Registration date: **2019-05-08, 1398/02/18**

Registration timing: **prospective**

Last update: **2019-05-08, 1398/02/18**

Update count: **0**

Registration date

2019-05-08, 1398/02/18

Registrant information

Name

Mohammad Azad manjiri

Name of organization / entity

Country

Iran (Islamic Republic of)

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manjirim1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2021-05-22, 1400/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Etiology and pathogenesis of kidney Stone formation

from the Perspective of Persian Medicine and Clinical evaluating of cynodon dactylon and dolichos biflorus extracts on Kidney Stone.

Public title

effect of cynodon dactylon and dolichos biflorus in kidney stone

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

20 to 60 years old The kidney stone is larger than 5 mm with sonography satisfaction of traditional treatments. Lack of history of chronic kidney disease

Exclusion criteria:

Pregnancy for women Medium to high hydronephrosis Acute renal diseases such as renal failure Severe urogenital infection

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation made by Random Allocation software is performed and the number of participants in each group are equal, and then the list of blocks and numbers are assigned to them, and then select random numbers and finally do the list of treatment allocation based on these numbers is marked as random.

Blinding (investigator's opinion)

Double blinded

Blinding description

People under study and assessors, researcher and watch out for clinical trials of the experimental and control groups will be unaware. This is the same form that drugs and placebo and a similar packaging by an analysis of data available to them in circumstances that placed its content is just a news analysis.

Placebo

Used

Assignment

Parallel

Other design features

In this study the effect of two herbal medicine on kidney stones is done in the event that they are useful as a proof of the effects of a new drug with low side effects, domestic production and commercialization as well as functionality and low cost.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

Street address

Qoreishi Building, Daneshgah Street

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Mashhad

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Razavi Khorasan

Postal code

9138813944

Approval date

2019-04-08, 1398/01/19

Ethics committee reference number

IR.MUMS.REC.1397.325

Health conditions studied**1****Description of health condition studied**

kidney stone

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes**1****Description**

The size of the Kidney stone and urinary ducts 5 mm and larger than 5 mm

Timepoint

The beginning of the study (before starting the intervention) and 21 days after starting taking cynodon dactylon and dolichos biflorus (Indian mung bean) extract

Method of measurement

Ultrasound

Secondary outcomes**1****Description**

Change (reduction) in the size of the stone and move or change the location of the stone (towards the bottom)

Timepoint

21 days after taking cynodon dactylon and Dolichous biflorus extract

Method of measurement

Ultrasound

Intervention groups

1

Description

The seed extract of dolichos biflorus with a dose of 1600 mg (daily 2 capsules 800 mg) will be given for 21 days.

Category

Treatment - Drugs

2

Description

Extracts of cynodon dactylon will be given with a dose of 1600 mg (daily 2 capsules 800 mg) for 21 days.

Category

Treatment - Drugs

3

Description

Control group: Daily 2 capsules of placebo for 21 days are given orally.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Mohammad Azad Manjiri

Street address

Imam Reza Sq., Ebne Sina Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Deputy of research and technology, Mashhad University of Medical Sciences, Daneshgah street

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Azad Manjiri

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Roshanak Salari

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Drug control

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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

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

If necessary and issuing the necessary license, only a
portion of the original outcome information is shared.

When the data will become available and for how long

Depending on the regulations of the university.

To whom data/document is available

Data will only be available to researchers working in
academic and scientific institutions.

Under which criteria data/document could be used

If necessary, researchers working in academic and
scientific institutions and licensing required by the
university

From where data/document is obtainable

Deputy of Research of Mashhad University of Medical
Sciences

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

Send a request to the university vice president of
research Carry out the necessary examinations Provide a
negative or positive result to the applicant

Comments