Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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Iran (Islamic Republic of)

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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
Province
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
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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
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Deputy of research and technology,Mashhad University of Medical Sciences,Daneshgah street Opposite of Daneshgah street 18
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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
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Other areas of specialty/work
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Person responsible for scientific

inquiries

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Full name of responsible person
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Assistant professor

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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 researchCarry out the necessary examinationsProvide a negative or positive result to the applicant

Comments