Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Investigating the herbal combination of Olea europaea leaf, Tribulus terrestris, Alhagi and zea mays on patients with kidney stone: a pre- and post-treatment comparative study

Protocol summary

Study aim

Investigating the herbal combination of olea europaea,tribulus terrestris Alhagi and zea mays(Z-Stone capsule) effects on reducing the formation of kidney stone or increasing the speed of stone excertion

Design

The study population includes 50 patient with kidney stone disease(stone size lesser than 10 milimeters). Patients will be devided into control and intervention group by chance(25 patients in each group). The study is phase 2 clinical trial. One month after treatment period, sonography and CT-Scan will be performed. The results of examining size, numbr and loation of stones in two groups will be compared.

Settings and conduct

The subjects for the study will be derived from the urology section of Imam Reza Hospital, Mashhad; and will be devided into control and intervention groups(25 patients in each group). Number, location and size of kindney stones will be assessed by sonography and CT-Scan, before and a month after intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: the desire to participate in the study; Patients with kidney stone; Stone size smaller than 10 milimeters; Exclusion criteria: history of kidney transplantation or other kidney diseases

Intervention groups

The patients recieve Z-Stone capsule equivalant to 2 grams mixture of olea europaea,tribulus terrestris Alhagi and zea mays with a glass of water, four times a day, each time 4 capsules, for a week. Control group recieve starch capsules(with a completley similar appearance to the Z-Stone) as placebo in the same way with intervention group.

Main outcome variables

Examining the number, size and location of kidney stone by sonography and CT-Scan

General information

Reason for update

The information is updated in order to changing the center of sampling, revising variables and considering the control group in this study.

Acronym

IRCT registration information

IRCT registration number: **IRCT20151230025772N6**
Registration date: **2019-11-23, 1398/09/02**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-18, 1399/05/28**
Update count: **2**

Registration date

2019-11-23, 1398/09/02

Registrant information

Name
Seyyed Abbas Zojaji
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 51 3711 2717
Email address
zojajia881@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-10-22, 1399/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the herbal combination of Olea europaea leaf, Tribulus terrestris, Alhagi and zea mays on patients with kidney stone: a pre- and post-treatment comparative study

Public title

Evaluation of the effects of a Polyherbal compound in the treatment of kindney stone disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The desire to participate in the study Patients with kidney stone Stone size lesser than 10 milimeters

Exclusion criteria:

Kidney tranplantation or other kidney diseases

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad university-Mashhad branch

Street address

Emam Khomeini Ave, Shahinfar Medical School

City

Mashhad

Province

Razavi Khorasan

Postal code

9187147578

Approval date

2019-06-26, 1398/04/05

Ethics committee reference number

IR.IAU.MSHD.REC.1398.063

Health conditions studied

1

Description of health condition studied

Kidney stone(urolithiasis)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Kidney stone size

Timepoint

Before intervention, one month after intervention

Method of measurement

1-Sonography, 2-Computed Tomography(CT scan)

2

Description

location of kidney stone

Timepoint

Before intervention, one month after intervention

Method of measurement

1-Sonography, 2-Computed Tomography(CT scan)

3

Description

Number of kidney stone

Timepoint

Before intervention, one month after intervention

Method of measurement

1-Sonography, 2-Computed Tomography(CT scan)

Secondary outcomes

empty

Intervention groups

1

Description

Volunteer patients recieve four capsules of Z-Stone (mixture of Olea europaea, Tribulus terrestires, Alhagi and Zea Mays) with a glass of water, four times a day, for a week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza hospital
Full name of responsible person
Seyyed Abbas Zojaji
Street address
Imam Reza Hospital, Imam Reza Square
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University
Full name of responsible person
Mohammad Reza Khakzad Oryani
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Innovative medical research center, Shahinfar university of medical science, Imam Khomeini Ave, Mashhad
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Zojaj Darman Tous Company

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Zojaj Darman Tous Company
Full name of responsible person
Seyyed Abbas Zojaji
Position
Ph.D of Pharmacology/CEO
Latest degree
Ph.D.
Other areas of specialty/work
Medical pharmacy
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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