Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of caltrop (Tribulus terristris) aqueous extract on 6-10 mm renal stones: a double blind randomized clinical trial

Protocol summary

Study aim

This study is designed to determine dissolving Effects of prepared drug based on Caltrop on Renal Stones. The prepared drug and placebo will given to the patients with age between 18-60 and size of stone between 6-10 millimeter recognized by valid diagnostic tests. The primary outcome will be assessed by changing in stone size. At the term of study data gathered will analyzed by applying valid and reliable statistical tests

Design

For patients of this study, kidney and liver tests that will be done, there is asked to make CT-scan or sonography without any contrast from all of participants and then each patient will be put in one of intervention or placebo groups randomly. Drug or placebo that have been prepared as syrup will be individualized them among two months to take twice a day by 10 cc. The 1st and 2nd follow ups will be after 2nd week and so after 4th week by calling on, 3rd and 4th follow up will be after 6th and 8th week by interviews. In the last session in addition of visit, there will be studies on liver and kidney exams, sonography and CT-scan if required.

Settings and conduct

All participants will be visited by urologist and refer to researcher in the urology clinic of Hamadan Beheshti hospital.

Participants/Inclusion and exclusion criteria

Agreement of participant, the size of renal stones: between 6-10 mm, the number of stones: 1-3mm, the location of the stones: superior, middle and inferior calyxes, age between 18-60, normal renal and liver function test.

Intervention groups

Volunteer patients will receive 10cc caltrop , two times a day, for 2 month.

Main outcome variables

Checking of stones size; displacement or change of stones; excretion of kidney stones.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221225056918N1**
Registration date: **2023-02-18, 1401/11/29**
Registration timing: **prospective**

Last update: **2023-02-18, 1401/11/29**
Update count: **0**

Registration date

2023-02-18, 1401/11/29

Registrant information

Name

Hediyeh Amin

Name of organization / entity

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Iran (Islamic Republic of)

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+98 26 3277 4834

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-06, 1401/12/15

Expected recruitment end date

2023-09-06, 1402/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of caltrop (Tribulus terristris) aqueous extract on 6-10 mm renal stones: a double blind randomized clinical trial

Public title

The effect of caltrop extract on renal stones

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Renal stones between 6-10 mm (kidney sonography or spiral CT without contrast) Renal stones without simultaneous symptoms (uncontrollable pain and nausea and vomiting) or referral pain Number of stones: between 1-3 stones The stones localize upper, middle and lower calyxes Agreement of participant to inform consent and signing it’s written form before recruiting in the study. Age of participant between 18-60 yr both gender The participant don't use other herbal or chemical drugs that effect on renal stones (allopurinol, indinavir,). Normal LFT (SGOT,SGPT, Alkaline Phosphatase), Normal KFT(BUN, Cr)

Exclusion criteria:

Consumption other types of chemical or herbal drugs except those prescribed in this study; History of significant problems (diabetes mellitus, renal dysfunctions, hepatic dysfunctions and peptic ulcer) other procedures or emergency interventions Affecting by urinary stone complications (any grade of hydro-nephrosis and urinary tract infectious) Subjects intending to withdraw at any time during the course of study Pregnancy; Lactating sensitivity to Caltrop

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will do in the intervention and control groups by blocking method. Using the Excel sheet, we generated 32 group with the block size of 2 people in each. Finally, we use the "Random" command to calculate the probability for each group. By sorting the probability, we will select 64 people, each allocate to intervention or placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients and researchers are kept blind. Each patient will receive a sealed envelop containing the relevant code for the type of intervention. Patients will be prescribed to receive whether A or B pack. Therefore, although, the pharmacologist is not blind, the radiologist and other researchers from medical school will be blind. In addition, as both groups will receive medication, they are not aware of whether they have receive the placebo or new treatment.

Placebo

Used

Assignment

Parallel

Other design features

The study population includes 64 patient with kidney stone disease (stone size between 6-10 millimeters). Patients will be divided into control and intervention group by chance (32 patients in each group). The study is a double blind randomized clinical trial during 8 weeks. Initially the size and position of stones will be obtained by sonography or CT-Scan. At the end of study, sonography or CT-scan will be repeated. The results of examining size, number and location of stones in two groups will be compared.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan medical university

Street address

Shahid fahmideh Ave., Pajoohesh Sq.

City

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Hamadan

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6517838736

Approval date

2022-12-24, 1401/10/03

Ethics committee reference number

IR.UMSHA.REC.1401.838

Health conditions studied

1

Description of health condition studied

urolithiasis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Size of renal stones

Timepoint

Before intervention and two months after intervention

Method of measurement

Sonography or CT-scan without contrast

2

Description

Location of renal stones

Timepoint

Before inter vention and two months after intervention

Method of measurement

Sonography or CT-scan without contrast

3

Description

Number of stones

Timepoint

Before inter vention and two months after intervention

Method of measurement

Sonography or CT-scan without contrast

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Volunteers will take 10cc of caltrop syrup twice a day during two months.

Category

Treatment - Drugs

2

Description

Control group: Volunteers will take 10cc of placebo syrup twice a day during two months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Urology clinic of Shahid Beheshti hospital

Full name of responsible person

Hedyeh Amin

Street address

Shahid Beheshti hospital, No1, Eram Blvd., Ghaem Sq.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Mehdi Biglarkhani

Position

Associate professor

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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