

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of the effectiveness of Trachyspermum ammi hydro-alcoholic extract on indicators related to kidney stones (randomized double-blind clinical study)

Protocol summary

Study aim

Evaluation of efficacy of hydro-alcoholic extract as a supplementary natural medicine for relieving the symptoms of patients with kidney stones

Design

Clinical trial with control group, including parallel, double blind, randomized, in phase 2 on 100 patients. Rand function in Excel software was used for randomization.

Settings and conduct

Study would be done in Yalda clinic of Tehran University of Medical Sciences by randomized and double-blind method. Patients would be placed in a group receiving common therapy plus Ajwain drop or a group receiving common therapy plus placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18-70 year; Stone diameter less than 10 mm; Filling consent form.
Exclusion criteria: Pregnancy of Breastfeeding; Being a candidate for surgery or lithotripsy;
Hypercholesterolemia; Concurrent therapy with anti-coagulants or anti-platelets; cirrhosis of the liver;
Moderate to severe renal insufficiency.

Intervention groups

The first intervention group will receive tamsulosin, analgesic (NSAID and opioid if necessary), hydrochlorthiazide and pyridoxine plus drop containing Ajwain extract. The second intervention group will receive tamsulosin, analgesic (NSAID and opioid if necessary), hydrochlorthiazide and pyridoxine plus drop containing placebo.

Main outcome variables

Pain level based on Visual Analogue Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160306026938N15**

Registration date: **2022-12-07, 1401/09/16**

Registration timing: **prospective**

Last update: **2022-12-07, 1401/09/16**

Update count: **0**

Registration date

2022-12-07, 1401/09/16

Registrant information

Name

Mahdi Vazirian

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6412 1223

Email address

vazirian_m@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-21, 1401/09/30

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of Trachyspermum ammi

hydro-alcoholic extract on indicators related to kidney stones (randomized double-blind clinical study)

Public title
Efficacy of trachyspermum ammi hydro-alcoholic extract on kidney stone

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients should be between 18 to 70 years old The diameter of the patints' stone must be less than 10 mm Patient's informed consent to enter the study
Exclusion criteria:
 Pregnant and lactating patients Patient with hypercholesterolemia Patients that use anti-coagulant and anti-platelet medicine Patients with liver cirrhosis Patients with a stone diameter greater than 10 mm or a patient who is a candidate for lithotripsy or surgery Patients with moderate to severe renal insufficiency Patient dissatisfaction with continuing the study after enrollment

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
First, using the Random number generation plugin in Excel software, a table of random numbers from 1 to 100 is prepared in a non-sequential and scattered manner, and the numbers are assigned to two intervention and control groups of 50 cases. The randomization process is performed by the methodology consultant and clinical researchers are not aware of the randomization process and will only be provided with random codes from 1 to 100.

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient will take the drug (intervention or comparison group) in closed envelopes that code receives are categorized. Coding by one of the project collaborators It takes place and they are the doctor, the evaluator and the patient.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Emam khomeini dospital of tehran University of Medical Sciences

Street address

Imam Khomeini Hospital Complex, Tohid Squire, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2021-03-07, 1399/12/17

Ethics committee reference number

IR.TUMS.IKHC.REC.1399.503

2

Ethics committee

Name of ethics committee

Research Ethichs Committees of The Institute of Pharmaceutical Sciences- Tehran University Of Medica

Street address

16 Azar Avenue, Tehran University of Medical Sciences, Faculty of Pharmacy, The Institute of Pharmaceutical Sciences, 2nd floor, Unit 1-219.

City

Tehran

Province

Tehran

Postal code

1417613151

Approval date

2021-10-11, 1400/07/19

Ethics committee reference number

IR.TUMS.TIPS.REC.1400.196

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

Patient's pain

Timepoint

At the beginning of the study (before beginning of intervention) and 7, 14, 21 and 28 days after beginning of intervention

Method of measurement

Scoring patients based on Visual Analogue Scale from 0 to 10

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receiving a drop containing Ajwain extract (in which in each 30 drops are equivalent to one gram of plant fruit in the form of extract) which is taken orally in about 25 ml of lemon juice, in addition to one of the drug treatment protocols for kidney stones including tamsulosin (one 0.4 mg capsule per day), analgesic (non-steroidal anti-inflammatory and opioid if needed), hydrochlorothiazide (25 mg every 12 hours) and pyridoxine (40 mg tablets, once daily) For one month

Category

Treatment - Drugs

2

Description

Control group: Receiving an oral drop without active ingredient (containing one percent of a food colorant similar to the drug containing Ajwain) in the morning, noon and night, 30 drops in half a glass of lemon juice each time, plus one of the treatment protocols for kidney stones including tamsulosin (one 0.4 mg capsule daily), analgesics (NSAIDS and opioids if needed), hydrochlorothiazide tablet (25 mg every 12 hours) and pyridoxine tablet (40 mg, once daily) for one month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Azam Alamdari

Street address

Imam Khomeini Hospital Complex, Tohid Squire, Tehran, Iran

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Tehran

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Phone

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Email

imamhospital@tums.ac.ir

Web page address

<http://ikhc.tums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Central organization of Tehran university of medical sciences, corner of Ghods Ave., Keshavarz Boulevard

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Tehran

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1417653761

Phone

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Email

vcr@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mahdi vazirian

Position

Assistant profssor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Pharmacognosy Lab., Second Floor, New building,
Faculty of Pharmacy, In front of Oruji Alley, 16th Azar
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Email

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mahdi vazirian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mahdi vazirian

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

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

Information about the primary outcome can be shared

When the data will become available and for how long

Access started from 2023

To whom data/document is available

Researchers working in academic and scientific
institutions will be allowed to access the data

Under which criteria data/document could be used

The data can be used for further research

From where data/document is obtainable

Receiving data will be possible via Dr. Mehdi Vazirian by
E-mail address of: mehdivazirian@gmail.com

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

After receiving the E-mail and confirming the identity of
the sender of the request, the data will be sent to the
person for a maximum of one month.

Comments