

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Apium graveolens and Pimpinella anisum herbal product on urinary tract stones

Protocol summary

Study aim

Determining the effect of Apium graveolens and Pimpinella anisum products on urinary tract stones

Design

Clinical trial with control and intervention groups, double blind, random sampling available

Settings and conduct

Random sampling is performed on patients who have been referred to 9Day Hospital Torbat Heydariyeh with a previous diagnosis of urinary stones. Neither analyst nor participant will be informed about group allocation. Patients in the intervention group of Ninety Apium graveolens-Pimpinella anisum 500 mg capsules produced by Sanabol Drug Company (in addition to taking the medications required for conventional medicine) were given for one month and the control group was monitored by the researcher and only their common medications (If needed). Anise-celery capsules are taken by patients in the intervention group three times in the morning, noon and night after meals, and the researcher will monitor the correct use of the drug on a weekly basis by telephone. After one month, Ultrasonography will be performed for both groups and the size of the urinary stone will be measured in millimeters.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The tendency to enter the study with kidney and bladder stones with a size equal to or less than 10 mm
Exclusion criteria: Acute kidney pain and Sensitivity to the present herbal product

Intervention groups

Intervention group : Ninety 500 mg Apium graveolens-Pimpinella anisum capsules produced by Sanabel Drug Company (in addition to the drugs required by conventional medicine) are given for one month in three shifts, morning, noon and night. Control group : monitored by the researcher and only take their common medicine (if needed).

Main outcome variables

Urinary stone size

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160516027925N6**

Registration date: **2020-04-29, 1399/02/10**

Registration timing: **prospective**

Last update: **2020-04-29, 1399/02/10**

Update count: **0**

Registration date

2020-04-29, 1399/02/10

Registrant information

Name

Amir Zoka

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3822 4395

Email address

zokaa921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-20, 1399/03/31

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Apium graveolens and Pimpinella anisum herbal product on urinary tract stones

Public title

Effect of Apium graveolens and Pimpinella anisum herbal medicine on urinary tract stones

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The tendency to enter the study with kidney and bladder stones with a size less than or equal to 10mm

Exclusion criteria:

Acute kidney pain Sensitivity to the present herbal product

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomized (using Randomization.com site) will be divided into Two groups: A (intervention) and B (control).

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will not know which group they are in. The data analyst and the outcome assessor will also be unaware of which group are intervention or control group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Torbate Heydariye University of Medical science

Street address

University of medical science, Razi Street

City

Torbat Heydariyeh

Province

Razavi Khorasan

Postal code

۹۵۱۶۹۱۵۱۶۹

Approval date

2020-01-24, 1398/11/04

Ethics committee reference number

IR.THUMS.REC.1398.047

Health conditions studied

1

Description of health condition studied

Urinary tract stones

ICD-10 code

N20

ICD-10 code description

Calculus of kidney and ureter

Primary outcomes

1

Description

Change of the size of the stone

Timepoint

Before and after the intervention

Method of measurement

Ultrasonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group : Ninety 500 mg Apium graveolens-Pimpinella anisum capsules produced by Sanabel Drug Company (in addition to the drugs required by conventional medicine) are given for one month in three shifts, morning, noon and night.

Category

Treatment - Other

2

Description

Control group: monitored by the researcher and only take their common medicine (if needed).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

9day hospital Torbat Heydariyeh

Full name of responsible person

Hosein Aziz

Street address

Kashani Street, 9day hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Hasan Azhdari Zarmehri

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Razi 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

Torbate-Heidaria 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

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Hossein Bakhtiari Dovombaygi

Position

Undergraduate Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Hosein Azizi

Position

Non-faculty physician

Latest degree

Specialist

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

Contact

Name of organization / entity

Torbate-Heidaria University of Medical Sciences

Full name of responsible person

Hossein Bakhtiari Dovombaygi

Position

Undergraduate Nursing Student

Latest degree

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Other areas of specialty/work

Nursery

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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