

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

comparison of hydrophilic extract of *Alhagi maurorum* and Hydrochlorothiazide in treatment of kidney and ureteral stones sized 4-10mm in patients older than 15 years old

Protocol summary

Study aim

comparison efficacy of hydrophilic extract of *Alhagi maurorum* and Hydrochlorothiazide in treatment of kidney and ureteral stones (4-10mm) in Shahid Mofateh clinic of Yasuj in 2018-2019

Design

In this randomized clinical trial from February 2018 to 2019 with simple sampling methods eighty (80) patients older than 15 years old suffering from renal or ureteral stones sized 4-10 millimeter with simple sampling method allocated in one of two groups.

Settings and conduct

Patients referring to Shahid Mofateh clinic of Yasuj sized 4-10 millimeter after taking informed consent form entered the study.

Participants/Inclusion and exclusion criteria

Patients older than 15 years old with kidney and ureteral stones sized 5-10 mm after taking informed consent form and approval of the ethics committee included in the study. Patients with severe cardiovascular and pulmonary disease, azotemia, urinary tract infection, coagulopathy, pregnant ladies and those that have a history of herbal or medicinal allergy don't enter the study.

Intervention groups

In first group one tablet of hydrochlorothiazide 25 mg will be prescribed every 12 hours with one glass of water for two weeks. In the second group 1 gram of extract in the form of capsule will be prescribed in 2 divided doses with one glass of water every 12 hours for two weeks.

Main outcome variables

efficacy of treatment according to change in the size of stone and passage of stones by KUB and ultrasonography before and after ESWL and during taking drugs till two weeks after intervention

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20081011001323N14**

Registration date: **2018-03-10, 1396/12/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-10, 1396/12/19**

Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

Sadrollah Mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3334 6070

Email address

dr.mehrabi@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-20, 1396/12/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of hydrophilic extract of Alhagi maurorum and Hydrochlorothiazide in treatment of kidney and ureteral stones sized 4_10mm in patients older than 15 years old

Public title

Comparison of Alhagi maurorum and Hydrochlorothiazide in treatment of kidney and ureteral stones

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age older than 15 years have renal or ureteral stones between 4-10 millimeter Have the consent to enter the study

Exclusion criteria:

Azotemia Pregnancy Presence of active urinary tract infection Allergy to medical or herbal drugs Severe cardiovascular or pulmonary disease Uncontrolled coagulopathy

Age

From 15 years old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized allocation with simple sampling method to intervention and controlled groups

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yasuj University of Medical Sciences

Street address

Yasuj University of Medical Sciences, Mottahari srteet, Yasuj , Iran

City

Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591741417

Approval date

2018-02-07, 1396/11/18

Ethics committee reference number

IR.YUMS.REC.1396.178

Health conditions studied

1

Description of health condition studied

Calculus of kidney and ureter

ICD-10 code

N20.2

ICD-10 code description

Calculus of kidney and calculus of ureter

Primary outcomes

1

Description

Expulsion of renal and ureteral stones sized 5-10 millimeter

Timepoint

Two weeks after the lithotripsy and treatment

Method of measurement

KUB and Ultrasonography and report of patients

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Capsule of Alhagi maurorum 500 miligram use with a glass of water every 12 hours for two weeks.

Category

Treatment - Drugs

2

Description

Control group: Hydrochlorothiazide Tablets 25 miligram every 12 hour with a glass of water for will used fortwo weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mofateh clinic of Yasuj

Full name of responsible person

Sadrollah Mehrabi

Street address

Montazeri street, Shahid Mofateh clinic, Yasuj, Iran

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dr.mehrabi@yums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Hosain Oriad, Research Vice Chancellor of university

Street address

Mottahari street, Research Vice Chancellor, Yasuj
University of Medical Sciences, Yasuj, Iran

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health.epid@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Yasuj 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

Yasuj University of Medical Sciences

Full name of responsible person

Sadrollah Mehrabi

Position

professor, Fellowship of endourology and laparoscopy

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Mottahari street, Education vice chancellor, Yasuj
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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