Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

The effect of Alhagi Pseudalhagi distillate on ureteral stone expulsion

Protocol summary

Summary

This single blind randomized clinical trial is conducted on 100 renal colic patients with ureteral stones less than 6 mm, from 23/09/2009 to 20/03/2010. After obtaining written consent all patients receive Hydrochlorothiazide (25 mg/day), Tamsulosin (0.4 mg/day), and analgesics and through simple randomization half of them also receive 150 ml/day Alhagi Pseudalhagi distillate from "Padina Natural Products, Mashhad" in 3 divided doses in addition to aforementioned drugs. All patients are visited again 2 weeks later and those with non-descent of stone, progressive hydronephrosis, or severe and unbearable symptoms are treated as medical treatment failures. Otherwise, the patients are followed for another 2 weeks and if at the end of the four-week period no stone is passed they will be categorized as no-stone-pass at the end of treatment. The stone expulsion rate and the time required for that will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138804172134N1**
Registration date: **2009-12-29, 1388/10/08**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-12-29, 1388/10/08

Registrant information

Name
Ali Cyrus
Name of organization / entity
Arak University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences, Deputy of Research

Expected recruitment start date

2009-09-23, 1388/07/01

Expected recruitment end date

2010-03-20, 1388/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Alhagi Pseudalhagi distillate on ureteral stone expulsion

Public title

The effect of Alhagi Pseudalhagi distillate on ureteral stone expulsion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: having ureteral stones 6 mm, not severe hydronephrosis, age more than 20 yr and less than 60 yr, no signs of UTI or fever according to physical findings and urine analysis, no known renal diseases according to history and preliminary laboratory exams, no mandatory restriction of fluids due to an underlying disease, no bilateral ureteral stones, not having a single kidney, no known allergic reaction to Alhagi Pseudalhagi distillate or gum, not being pregnant, and body weight between 50 to 100 kg. Exclusion criteria: patients' reluctance to continue participating in the study, no follow up visits, progressive hydronephrosis during follow up, occurrence of fever or UTI during follow up, repeated

bouts of unbearable ureteral colics during follow up, allergic reactions or complications due to the treatment.

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Arak University of Medical Sciences

Street address
Pardis Complex, Basij Square, Enghelab Square, Taleghani Ave.

City
Arak

Postal code

Approval date
2008-10-29, 1387/08/08

Ethics committee reference number
87-42-5

Health conditions studied

1

Description of health condition studied
Ureteral stone

ICD-10 code
N20.1

ICD-10 code description
Calculus of ureter

Primary outcomes

1

Description
Ureteral stone passage

Timepoint
2 and 4 weeks after commencement of therapy

Method of measurement
According to patients' report

Secondary outcomes

1

Description
Time to stone passage

Timepoint
2 and 4 weeks after commencement of therapy

Method of measurement
by asking the patients

Intervention groups

1

Description
The control group receive Hydrochlorothiazide (25 mg/day), Tamsulosin (0.4 mg/day), Diclofenac sodium suppository (100 mg PRN), and Tramadol inj. (50 mg IM PRN).

Category
Treatment - Drugs

2

Description
The intervention group receive Hydrochlorothiazide tablets (25 mg/day), Tamsulosin capsules (0.4 mg/day), Diclofenac sodium suppository (100 mg PRN), Tramadol inj. (50 mg IM PRN), and 150 ml/day Alhagi Pseudalhagi distillate from "Padina Natural Products, Mashhad" in 3 divided doses.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Arak Vali Asr Hospital

Full name of responsible person
Dr. Ali Cyrus

Street address
Department of Surgery, Vali-Asr Hospital, Vali-Asr Square

City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr. Saeed Changizie Ashtiani
Street address
Pardis Complex, Basij Square, Enghelab Square, Taleghani Ave.
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
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Position
Urologist/Associate professor
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Person responsible for updating data

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty