

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

Country

Iran (Islamic Republic of)

Phone

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Email address

cyrus@arakmu.ac.ir

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 \leq 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.

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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

Full name of responsible person

Dr. Ali Cyrus

Position

Urologist/Associate professor

Other areas of specialty/work**Street address**

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Person responsible for updating data

Contact**Name of organization / entity**

Arak University of Medical Sciences

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Fax**Email****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