Clinical Trial Protocol
Iranian Registry of Clinical Trials
21 Apr 2020

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

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

Secondary 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 Changzie 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**
- empty

**Type of organization providing the funding**
- empty

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### 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**
- Department of Surgery, Vali-Asr Hospital, Vali-Asr Square

**City**
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### Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
- Arak University of Medical Sciences

**Full name of responsible person**
- Dr. Ali Cyrus

**Position**

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### 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