Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Alhagi distillate on ureteral stone expulsion

Protocol summary

Study aim
Evaluation of the effect of Alhagi distillate on ureteral stone expulsion

Design
This study is a clinical trial. In this study, 110 patients will be randomly divided into intervention and control groups.

Settings and conduct
In this study, the patients referred to the special clinic of the 22 Bahman Hospital in Neyshabur who have been diagnosed with secondary renal colic in the ureter have been introduced and included in the research units.Patients in this study were examined through the diagnosis of a urologist by methods such as taking kidney, ureter, and bladder (KUB) images, sonography, and full urine analysis. The stone size and location were detected and recorded.At the beginning of the study, the patients were asked about the history of drug use, so that they did not enter the design if those drugs interfered with the Alhagi Pseudalhagi distillate. Moreover, patients with a history of use of an herbal medicine effective on stone removal before their referral to the doctor, did not enter the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having consent form, Ureteral stones smaller than 1 cm, All patients with renal colic pain with kidney stones diagnosis, Age between 20 and 60 years. Exclusion criteria: Severe or progressive Hydronephrosis, Urinary tract infection, The patients symptoms can not be tolerated.

Intervention groups
In this study, patients in the control group daily received one 0.4 mg tamsulosin capsule(Farabi Pharmacy), diclofenac suppositories of 100 mg(Sobhan Pharmacy) and Cefixime 200 mg(Farabi Pharmacy) every twelve hours (routine intervention determined by a physician based on American nephrology protocols). The intervention group, in addition to receiving routine treatments, will receive 150 cc of Alhagi distillate(Qadah Kashan co) daily in 3 divided doses for a period of 4 weeks.

Main outcome variables
Rate of ureteral stone expulsion

General information

Reason for update
Correction of the start and end date of the enrollment

Acronym

IRCT registration information
IRCT registration number: **IRCT20150511022218N5**
Registration date: **2019-04-06, 1398/01/17**
Registration timing: **prospective**

Last update: **2022-02-24, 1400/12/05**
Update count: **1**

Registration date
2019-04-06, 1398/01/17

Registrant information

Name
Vahid Moeini Ghamchini

Name of organization / entity
Neyshabour University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2019-09-23, 1398/07/01

Actual recruitment start date
2019-07-23, 1398/05/01

Actual recruitment end date

2019-09-23, 1398/07/01

Trial completion date

2019-09-23, 1398/07/01

Scientific title

The effect of Alhagi distillate on ureteral stone expulsion

Public title

The effect of Alhagi distillate on ureteral stone expulsion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having Consent form All patients with renal colic pain with kidney stones diagnosis Ureteral stones smaller than 1 cm Age between 20 and 60 years

Exclusion criteria:

Severe or progressive hydronephrosis Urinary tract infection The patient's symptoms can not be tolerated

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **110**

Actual sample size reached: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

In the present study, the subjects were divided into intervention and control groups in blocks of 4 using randomized block method. For this purpose, first, all possible states were assigned, as half of the subjects to group A (intervention group) and the other half to group B (control group), including AABB, BBAA, ABAB, BABA, ABBA, BAAB. Then, one of the digits 1 to 6 was assigned to each of the combinations of 4, and choices from 1 to 6 were randomly selected with replacement. The selected blocks were recorded as a serial sequence. Each individual entering the study received a treatment A or B in terms of sequence. Random selection of the blocks continued until reaching the sample size of the study

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 Neyshabur University of Medical Sciences

Street address

Neyshabur University of Medical Sciences, Janbazan Blvd, Qods Town, Neyshabur

City

Neyshabur

Province

Razavi Khorasan

Postal code

6623451124

Approval date

2018-04-15, 1397/01/26

Ethics committee reference number

IR.NUMS.REC.1397.003

Health conditions studied

1

Description of health condition studied

ureteral stone

ICD-10 code

N21

ICD-10 code description

Calculus of lower urinary tract

Primary outcomes

1

Description

The amount of stone disposal

Timepoint

Check the presence and exact location of the stone before the intervention and one week after the intervention.

Method of measurement

Using a checklist that includes: Clinical examination, patient interview, and ultrasound.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this study The intervention group, in addition to receiving routine treatments (daily one 0.4 mg tamsulosin capsule(Farabi Pharmacy), diclofenac suppositories of 100 mg(Sobhan Pharmacy) and Cefixime 200 mg(Farabi Pharmacy) every twelve hours), will receive 150 cc of Alhagi distillate(Qadah Kashan Co) daily in 3 divided doses for a period of 4 weeks.

Category

Treatment - Other

2

Description
Control group:In this study, patients in the control group daily received one 0.4 mg tamsulosin capsule(Farabi Pharmacy), diclofenac suppositories of 100 mg(Sobhan Pharmacy) and Cefixime 200 mg(Farabi Pharmacy) every twelve hours (routine intervention determined by a physician based on American nephrology protocols).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
22 Bahman Neyshabur Hospital
Full name of responsible person
Vahid Moeini
Street address
22 Bahman Neyshabur Hospital, Imam Khomeini Blvd,Imam Khomeini Square,Neyshabur
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Neyshabour University of Medical Sciences
Full name of responsible person
Morteza Shamshirgaran
Street address
Neyshabur University of Medical Sciences, Janbazan Blvd, Qods Town, Neyshabur
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v.moini@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Neyshabour 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
Neyshabour University of Medical Sciences
Full name of responsible person
Vahid Moeini
Position
Faculty member
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
The researcher only intends to publish the article and there is no plan for publication in this study
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available