

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 4261 4062

###### Email address

v.moinighamchini@arakmu.ac.ir

##### 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

##### City

Neyshabur

##### Province

Razavi Khorasan

##### Postal code

6623451124

##### Phone

+98 51 4334 4711

##### Fax

+98 51 4262 7500

##### Email

info@nums.ac.ir

## 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

##### City

Neyshabour

##### Province

Razavi Khorasan

##### Postal code

6623451124

##### Phone

+98 51 4334 4711

##### Email

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

Master

##### Other areas of specialty/work

Nursery

##### Street address

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

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##### Province

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##### Postal code

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+98 51 4334 4711

##### Email

v.moini@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Neyshabour University of Medical Sciences

##### Full name of responsible person

Vahid Moeini

##### Position

Faculty member

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

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v.moini@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Neyshabour University of Medical Sciences  
**Full name of responsible person**  
Vahid Moeini  
**Position**  
Faculty member  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nursery  
**Street address**  
Neyshabur University of Medical Sciences, Janbazan  
Blvd, Qods Town, Neyshabur  
**City**

## 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