Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Alhagi maurorum distillate on renal and upper ureteral stones expulsion after Extracorporeal shock wave lithotripsy (ESWL): randomized clinical trial

Protocol summary

Study aim

Determining the effect of Harsh sweat on excretion of kidney and upper ureteral stones after extracorporeal lithotripsy

Design

This study is a randomized clinical trial. Patients referred to the specialized clinic of 22 Bahman Hospital in Neyshabour who are diagnosed with renal colic secondary to urinary stones. In this study, 140 patients will be randomly divided into intervention and control groups.

Settings and conduct

Patients referred to the specialized clinic of 22 Bahman Hospital in Neyshabour who are diagnosed with renal colic secondary to urinary stones will be examined. In this study, patients will be examined by a urologist and by methods such as KUB, ultrasound, CT scan and in some cases by intravenous urography, complete urinalysis and routine blood tests. The size of the stone and its location will be identified and recorded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: complete the informed consent form; age between 18 and 70 years old; stones with a diameter between 5-20 mm; stones in the pelvis, middle and upper calyx (other than lower calyx). Exclusion criteria: patient's unwillingness to continue cooperation; pregnancy; uncontrolled urinary tract infections; patients with coagulation problems Severe spinal deformities; patients with gastric ulcer problem (because the use of painkillers exacerbates this problem); severe hydronephrosis; inadequate renal function (creatinine above 2 mg /dL); BMI above 30; ESWL history unsuccessful; history of surgery on the urinary system; abdominal aortic and renal artery aneurysms; patients taking alpha blocker or calcium blocker.

Intervention groups

Patients in the control group will receive one capsule of tamsulosin 0.4 mg daily and 100 mg diclofenac suppository daily. Patients in the intervention group, in addition to receiving routine treatments, will receive 150 cc of Haresht sweat daily in 3 divided doses.

Main outcome variables

Rate of stone expulsion after ESWL

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150511022218N6**
Registration date: **2022-06-25, 1401/04/04**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-25, 1401/04/04**
Update count: **0**

Registration date

2022-06-25, 1401/04/04

Registrant information

Name

Vahid Moeini Ghamchini

Name of organization / entity

Neyshabour University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date
2022-10-23, 1401/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Alhagi maurorum distillate on renal and upper ureteral stones expulsion after Extracorporeal shock wave lithotripsy (ESWL): randomized clinical trial

Public title
The effect of Alhagi maurorum distillate on renal and upper ureteral stones expulsion after Extracorporeal shock wave lithotripsy (ESWL): randomized clinical trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Signing consent form Age between 18 and 60 years Stones with a diameter between 5-20 mm Stones in the pelvis, middle and upper calyx (except lower calyx)
Exclusion criteria:
The patient's unwillingness to continue cooperating Pregnancy Uncontrolled urinary tract infection Patients with coagulation problems Severe spinal deformities Patients with gastric ulcer problem (because the use of painkillers exacerbates this problem) Severe hydronephrosis Inadequate renal function (creatinine above 2 mg / dL) BMI above 30 ESWL history unsuccessful History of urinary tract surgery Abdominal aortic and renal artery aneurysms Patients taking alpha blocker or calcium blocker
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **140**
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
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Neyshabur
Province
Razavi Khorasan
Postal code
6623451124
Approval date
2022-02-22, 1400/12/03
Ethics committee reference number
IR.NUMS.REC.1400.049

Health conditions studied

1

Description of health condition studied
kidney stone
ICD-10 code
N20
ICD-10 code description
Calculus of kidney and ureter

Primary outcomes

1

Description
Rate of the stone expulsion
Timepoint
Interventions will begin the day before the ESWL process and will continue daily until the stone is expelled. Stone removal In this study, we define complete stone removal or the remaining broken pieces of stone less than 3 mm during the two weeks to three months after the procedure.
Method of measurement
En 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), will receive 150 cc of Alhagi distillate daily in 3 divided doses. They will consume from the day before the intervention until the stone is expulsion.
Category
Treatment - Other

2

Description
Control group: patients in the control group will receive one capsule of tamsulosin 0.4 mg daily and 100 mg diclofenac suppository daily.
Category
Treatment - Other

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
Ali Akbar Mohammadi
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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
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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