

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 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

City

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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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

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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