

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The effect of acupressure on the intensity of nausea, pain and physiological parameters of patients treated with extracorporeal lithotripsy

#### Protocol summary

##### Study aim

The effect of acupressure in point Qiu on the intensity of nausea, pain and physiological parameters of patients treated with extracorporeal lithotripsy is investigated.

##### Design

Clinical trial with control group, with parallel groups, Double blind, randomized from available samples, phase 3 on 70 patients. A block method was used for randomization.

##### Settings and conduct

Patients treated with extracorporeal lithotripsy referred to Shahid Beheshti Hospital in Hamadan were randomly divided into intervention and control groups. The patients in the intervention group lie on the opposite side of the side that has pain, and the exact location of the Qiu point is determined, and force is applied to the spine with the thumb for 3 minutes in the direction of 45 degrees. The strength of the thumb increases gradually and with a regular rhythm until the patient feels warmth in the area.

##### Participants/Inclusion and exclusion criteria

Entry conditions: 1) extracorporeal lithotripsy candidate 2) Age range 18 to 65 years 3) Perform extracorporeal lithotripsy for the first time 4) Signing an informed consent form. No entry conditions: 1) Have previous experience or knowledge of the effects of acupressure 2) Drug addiction 4) Existence of an obstacle at the site of pressure (wounds, skin diseases, etc)

##### Intervention groups

Study groups: Intervention group: In the intervention group, the massage intervention is performed at the Qiu acupuncture point located around the lumbocostal region for 3 minutes. The main outcome variables include the severity of nausea, pain and physiological indicators (including heart rate and blood pressure) of the patients are recorded. Control group: In the control group, massage intervention is performed in the neutral area

and around the main point. Patients in both groups receive routine care.

##### Main outcome variables

Nausea, pain and physiological parameters

#### General information

##### Reason for update

Update based on pilot study results

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190524043687N4**

Registration date: **2023-05-03, 1402/02/13**

Registration timing: **prospective**

Last update: **2024-01-10, 1402/10/20**

Update count: **1**

##### Registration date

2023-05-03, 1402/02/13

##### Registrant information

###### Name

Ali Safdari

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 5861 5962

###### Email address

asafdari.nu@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-22, 1402/03/01

##### Expected recruitment end date

2024-03-20, 1403/01/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of acupressure on the intensity of nausea, pain and physiological parameters of patients treated with extracorporeal lithotripsy

**Public title**

The effect of acupressure on the intensity of nausea, pain and physiological parameters of patients treated with extracorporeal lithotripsy

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Eligible for with extracorporeal lithotripsy according to the doctor's diagnosis Signing an informed consent form The age range of 18 to 65 Perform extracorporeal lithotripsy for the first time

**Exclusion criteria:**

Have previous experience or knowledge of the effects of acupressure Lack of full consciousness Having mental, visual and auditory disorders and neuropathy Drug addiction Existence of an obstacle at the site of pressure (wounds, skin diseases, etc)

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **70**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization method: Block randomization method with unequal blocks. will be used - Randomization unit: individual - How to build a random sequence: An equal number of each group will be placed in each block. In this way, first, the list of all permutations related to the size of the desired block is determined and then will be randomly as many as the number of samples from the permutation. The method used to generate the random allocation sequence is using a computer. The method of concealing the allocation is to use sealed envelopes.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The blind groups in this study include patients and an assistant research collector; in such a way that none of

the patients and the data collector will be aware of the allocation of patients to the two intervention and control groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Research Ethical Committee of Hamadan University of Medical Sciences

**Street address**

Hamadan University of Medical Science, Shahid Fahmide Boulevard, Hamadan, Iran

**City**

Hamadan

**Province**

Hamadan

**Postal code**

6517838736

**Approval date**

2023-04-29, 1402/02/09

**Ethics committee reference number**

IR.UMSHA.REC.1402.058

**Health conditions studied****1****Description of health condition studied**

Urinary stones

**ICD-10 code**

N20.0

**ICD-10 code description**

Calculus of kidney

**Primary outcomes****1****Description**

Intensity of pain

**Timepoint**

Before intervention, 1, 10, 20, 30, 40 and 50 minutes after the intervention

**Method of measurement**

Numeric pain rating scale

**2****Description**

Intensity of nausea

### **Timepoint**

The intensity of nausea will be evaluated before and after extracorporeal shock wave lithotripsy

### **Method of measurement**

Self-report scale

### **3**

#### **Description**

Heart rate

#### **Timepoint**

Before intervention, 1, 10, 20, 30, 40 and 50 minutes after the intervention

#### **Method of measurement**

Number of beats per minute - pulse oximeter

### **4**

#### **Description**

Blood pressure

#### **Timepoint**

Before intervention, 1, 10, 20, 30, 40 and 50 minutes after the intervention

#### **Method of measurement**

By sphygmomanometer

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Patients in the intervention group will receive the intervention before the extra-organ stone crushing in the same place in a room with minimal environmental stimuli (such as sound, temperature, light, etc.) while respecting privacy. For this purpose, the researcher first takes out his watch and ring and washes and warms his hands, then stretches the paravanes around the patient's bed and the patient lies on the opposite side that is in pain so that the painful side of the patient faces the side. be placed above the patient's knees are slightly bent into the abdomen. Acupressure intervention in the present study is performed at the acupuncture point of Qiu. This point was first identified by Yunqiao Qiu, a urology specialist at a hospital affiliated with Guangzhou Medical University in China, for treating acute kidney colic pain. This anatomical point is located about the width of one finger (the size of the body is equivalent to 1.3 inches) below and one thumb's width inside the intersection of the twelfth rib and the column of vertebrae (Lumbo-costal point). After observing the location choosing the exact location and marking it with his thumb, the researcher presses a force in the direction of 45 degrees to the spine for 3 minutes. Thumb strength will be done gradually and with a regular rhythm until the patient feels warmth in the area. The massage intervention will be repeated once exactly before the commencement of lithotripsy. The results examined in this study are measured before massage

and at 1, 10, 20, 30, 40, and 50 minutes.

### **Category**

Treatment - Other

### **2**

#### **Description**

Control group: In the control group, according to the protocol of the acupressure intervention group, they will receive massage intervention at the neutral point and around the main point.

### **Category**

Other

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Beheshti Hospital

##### **Full name of responsible person**

Dr. Habibullah Mousavi Bahar

##### **Street address**

Shahid Beheshti Medical Center, at the beginning of Eram Boulevard, Ghaem Square, Hamadan

##### **City**

Hamadan

##### **Province**

Hamadan

##### **Postal code**

3371565179

##### **Phone**

+98 81 3838 0283

##### **Email**

Shahidbeheshti@umsha.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Hamedan University of Medical Sciences

##### **Full name of responsible person**

Reza Shokouhi

##### **Street address**

Hamadan University of Medical Sciences, Shahid Fahmideh Street

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##### **Province**

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38698-65178

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##### **Email**

shokoohi@yahoo.com

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor**

**organization/entity?**

Yes

**Title of funding source**

Hamedan 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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Ali Safdari

**Position**

Master of science student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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asafdari.nu@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Seyed Reza Borzou

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

Master of science student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Fax****Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available