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)

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+98 86 5861 5962

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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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
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
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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