

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of acupressure on pain and anxiety in elderly female candidates for extracorporeal shock wave lithotripsy

Protocol summary

Study aim

Determining the effect of acupressure on pain and anxiety in elderly women candidates for extracorporeal lithotripsy

Design

In this triple-blind two arms parallel-group randomized trial, 66 patients are selected by convenience sampling and then randomly assigned to the intervention and control groups.

Settings and conduct

The statistical population of all elderly women will be candidates of lithotripsy referred to Isfahan Ordibehesht Surgery Center. The sample size of this study is 66 elderly women who are candidates for lithotripsy. The patient will be selected through the sampling method based on purpose and then will be randomly divided into two groups. In the intervention group, acupressure is applied using the index finger at points He7, Lu7, K1, LI4. They will be pressed twice for 20 minutes. In the control group, similar places will be performed in the intervention group with the same duration (without any pressure). In both groups, anxiety and pain are evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 60 years of age or older, the first experience of referring to a lithotripsy treatment program, not having any special problems on the spot of receiving acupressure, do not take painkillers for 24 hours before the intervention. Exclusion criteria: The person is not willing to continue working on the research project

Intervention groups

In the intervention group: acupressure will be done by a trained person's thumb on 4 points on both sides of the body. In the control group: In this group, similar places are performed in the intervention group with the same duration (without any pressure).

Main outcome variables

pain and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110912007529N24**

Registration date: **2022-05-02, 1401/02/12**

Registration timing: **retrospective**

Last update: **2022-05-02, 1401/02/12**

Update count: **0**

Registration date

2022-05-02, 1401/02/12

Registrant information

Name

Nahid Rejeh

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 3071

Email address

reje@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-01, 1400/09/10

Expected recruitment end date

2022-02-04, 1400/11/15

Actual recruitment start date

2021-12-01, 1400/09/10

Actual recruitment end date

2022-02-24, 1400/12/05

Trial completion date

2022-03-06, 1400/12/15

Scientific title

The effect of acupressure on pain and anxiety in elderly female candidates for extracorporeal shock wave lithotripsy

Public title

Investigating the effect of acupressure on improving pain and anxiety

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

60 years of age or older, ability to understand Persian, having adequate hearing and vision, no chronic neuropathic diseases, no cognitive impairment, The first experience of referring to a lithotripsy treatment program, no amputation of the limbs, no pain or sore in hands (at the place of acupressure), no dependence or addiction to any drugs, do not take sedatives and anti-anxiety drugs daily for more than a month, do not take painkillers for 24 hours before the intervention, do not take drugs that reduce or increase cortisol (for two weeks Before wave lithotripsy).

Exclusion criteria:

unwillingness to continue to participate in the study, patients who during acupressure in He7, Lu7, K1, LI4 does not feel hot, heavy, swollen or numb at this point

Age

From **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **66**

Actual sample size reached: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples were selected using a convenience sample method and were randomly allocated to two groups as intervention and control using the block randomization method with a block size of 4 and with a 2:2 assignment ratio. Randomization tool: <https://www.sealedenvelope.com/simple-randomiser/v1/lists>

Blinding (investigator's opinion)

Double blinded

Blinding description

In patients' control, similar places are performed in the intervention group with the same duration (without any pressure). The post-intervention information is collected by unbiased collaborations of the uninformed patients. Data analysis will be done by people who do not have the code information. Therefore patients and sampler and the statistical analyzer will be blind to patients 'allocation

of the groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahed University

Street address

Shahed university, Opposite Holy Shrine of Imam Khomeini, Tehran-Qom Expressway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2021-11-01, 1400/08/10

Ethics committee reference number

Shahed.REC.1400.091

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

Calculus of kidney

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

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

intensity of pain

Timepoint

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

Method of measurement

Visual Pain Scale

2**Description**

Quality of pain

Timepoint

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

Method of measurement

MacGill questionnaire

Secondary outcomes**1****Description**

Intensity of anxiety

Timepoint

The intensity of anxiety will be evaluated before intervention and after the intervention

Method of measurement

Visual Analogue Scale for Anxiety

2**Description**

Quality of anxiety

Timepoint

The intensity of anxiety will be evaluated before intervention and after the intervention.

Method of measurement

Spielberger

Intervention groups**1****Description**

Intervention group: In this group, acupressure by a trained person's thumb on 4 points on both sides of the body, including He7, Lu7, K1, LI4 (Hugo point, located on the back of the hand between bones 1 and 2 and on the radial side of the second metacarpal. The Lu7 point is located in the radial part of the forearm, above the styloid appendage of the ulnar bone, at a distance of 3.5 cm or 1.5 cun above the transverse crease of the wrist. The seventh heart point is located directly on the transverse crease of the wrist with the Carmen flexor tendon of the ulnar, and the K1 point is located at the junction of the anterior third, and posterior two-thirds of the sole (between the second and third toes) to reduce pain and Anxiety is used, where each point is pressed for 2 minutes and a total of 20 minutes and twice.

Category

Other

2**Description**

Control group: In this group, similar places are performed in the intervention group with the same duration (without any pressure).

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ordibehesht Surgery Center

Full name of responsible person

Fariba ziaei azarkhavarani

Street address

Ordibehesht Surgery Center, Roudaki St., Next to the Passport Office, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8176763379

Phone

+98 31 3786 1672

Email

faribaziyaei2020@yahoo.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahed University

Full name of responsible person

Shahriar Bijani

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5121 3564

Email

info@shahed.ac.ir

Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahed University

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

Shahed University

Full name of responsible person

Nahid Rejeh

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran Qom Express way, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

3319118651

Phone

+98 21 5121 3550

Email

nrejah@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Nahid Rejeh

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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3319118651

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+98 21 5121 3550

Email

nrejah@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahed University

Full name of responsible person

Nahid Rejeh

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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City

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Province

Tehran

Postal code

3319118651

Phone

+98 21 5121 3550

Fax**Email**

nrejah@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Not applicable

Informed Consent Form

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

some of the statistical data is available after being unidentifiable

When the data will become available and for how long

The access period is up to after the publication of the results.

To whom data/document is available

Data is available to academic researchers

Under which criteria data/document could be used

Use of information for academic research projects is allowed.

From where data/document is obtainable

Nahid Rejeh reje@shahed.ac.ir

What processes are involved for a request to access data/document

Requests for specific information should be sent by email.

Comments