Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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Iran (Islamic Republic of)

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+98 21 5121 3071

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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
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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
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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

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Person responsible for updating data

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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