

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of plantar reflexology on pain, anxiety and physiological parameters of patients undergoing extracorporeal lithotripsy

#### Protocol summary

##### Study aim

The effect of plantar reflexology on anxiety and physiological parameters of patients undergoing extracorporeal lithotripsy is investigated

##### Design

Clinical trial with control group, with parallel groups, without blinding, randomized from available samples, phase 3 on 74 patients. Blocked randomization was used for randomization

##### Settings and conduct

Massage for patients is performed by a same-sex researcher who will undergo reflexology training. The massage is performed 10 minutes after the patients enter the bed where they are hospitalized. Which will be performed in a room in a ward where the patient's privacy is observed and environmental stimuli are minimal. The reflexology procedure in this study is based on Fitzgerald methodology by the interventionist.

##### Participants/Inclusion and exclusion criteria

Entry requirements: Age range 18 to 65 years Perform extracorporeal lithotripsy for the first time No obstruction at the site of pressure (wounds, skin diseases, etc.) No entry conditions: Having previous experience or knowledge of the impact of acupressure Drug addiction Existence of sensory and motor disorders in the legs Allergy to olive oil

##### Intervention groups

In the intervention group, reflexology procedures are performed based on Fitzgerald methodology. The massage of the left foot lasts for 10 minutes (for each foot) at a slow pace, with a regular rhythm . 2 minutes are for general foot massage and in the next stage, reflex points on the sole, including the diaphragm, solar plexus, pituitary gland, lungs, and adrenal glands, were massaged.. Then the same steps are performed on the patient's right foot. In the control group, only routine care is performed.

##### Main outcome variables

Anxiety; pain ; Physiological parameters

#### General information

##### Reason for update

Changes in the randomization method, sample size, and duration of the trial and acupressure points that needed to be changed during the work process due to limitations

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190729044370N2**

Registration date: **2022-06-18, 1401/03/28**

Registration timing: **prospective**

Last update: **2024-03-05, 1402/12/15**

Update count: **1**

##### Registration date

2022-06-18, 1401/03/28

##### Registrant information

##### Name

zahra Borzabadi Farahani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3485 0603

##### Email address

farahani.z201625@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-02, 1401/04/11

##### Expected recruitment end date

2022-11-05, 1401/08/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The effect of plantar reflexology on pain, anxiety and physiological parameters of patients undergoing extracorporeal lithotripsy

### Public title

The effect of plantar reflexology on pain, anxiety and physiological parameters

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Signing the informed consent form Age range 18 to 65 years Perform extracorporeal lithotripsy for the first time Lack of previous experience or knowledge of the effects of acupressure Full consciousness, no mental, visual and auditory disorders No history of taking anti-anxiety and sedative drugs one week before participating in the study (based on the contents of the file) No drug addiction Have a minimum literacy to complete the questionnaire; No obstruction at the site of pressure (wounds, skin diseases, etc.) Absence of sensory and motor disorders in the legs and minimal ability to walk on the legs (peripheral neuropathy or vascular problems in the lower extremities) Lack of sensitivity to olive oil Body mass index (BMI) between 18.5 to 30 kg/m<sup>2</sup> Have an anxiety score of 43 or higher on the Spielberger scale

#### Exclusion criteria:

Failure to complete the patient procedure for any reason unwillingness to continue the intervention

### Age

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

### Gender

Both

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **74**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Due to the gradual entry of samples into the research in this study, Among the available patients, patients with equal number of members are assigned to each of the intervention and control groups by a blocked randomization design .

### 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

کمیته اخلاق دانشگاه علوم پزشکی اراک

##### Street address

اراک - خیابان شهید شبرودی - خیابان علم الهدی

##### City

Arak

##### Province

Markazi

##### Postal code

3819693345

#### Approval date

2022-05-17, 1401/02/27

#### Ethics committee reference number

IR.ARAKMU.REC.1401.044

## Health conditions studied

### 1

#### Description of health condition studied

The effect of plantar reflexology on pain, anxiety and physiological parameters

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Anxiety: Anxiety score in Spielberger questionnaire

#### Timepoint

Anxiety measurement will be done before and one hour after the start of the intervention

#### Method of measurement

The Spielberger Anxiety Inventory will be used to assess patients' anxiety. This questionnaire includes separate self-assessment scales to measure overt and covert anxiety.

### 2

#### Description

Pain: Pain intensity from 0 to 10

#### Timepoint

Pain measurement will be done before and after the start of the intervention

#### Method of measurement

The numerical pain scale is numbered from 0 to 10 (0 without pain and 10 maximum pain).

### 3

#### Description

Physiological parameters of patients including heart rate, respiration, systolic and diastolic blood pressure.

#### Timepoint

physiological parameters measurement will be done before and after the start of the intervention

#### Method of measurement

To measure the pulse rate and oxygen saturation of arterial blood with a pulse oximeter and to measure the number of breaths, after observing a complete respiratory cycle, including inhalation and exhalation, we count the number of breaths and to measure blood pressure use a sphygmomanometer.

#### Secondary outcomes

empty

#### Intervention groups

##### 1

#### Description

Control group: In the control group, only routine care is performed

#### Category

Other

#### Recruitment centers

##### 1

#### Recruitment center

##### Name of recruitment center

Amir Al-Momenin Hospital

##### Full name of responsible person

زهرا برزآبادی فراهانی

##### Street address

اراک، میدان بسیج، جنب دانشکده پزشکی

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3848176941

##### Phone

+98 86 3417 3601

##### Email

it-amiralmomenin@arakmu.ac.ir

##### Web page address

<https://arakmu.ac.ir/amirhos/fa>

#### Sponsors / Funding sources

##### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

زهرا برزآبادی فراهانی

##### Street address

Arak University of Medical Science, Basij Squa, Arakre

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##### Province

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##### Postal code

۳۸۱۹۶۹۳۳۴۰

##### Phone

+98 86 3313 6055

##### Email

info@arakmu.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Arak University of Medical Sciences

#### Proportion provided by this source

80

#### 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

Arak University of Medical Sciences

##### Full name of responsible person

Zahra Borzabadi Farahani

##### Position

Faculty member

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

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Arak University of medical science, Basij Square, Arak,

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farahani.z201625@gmail.com

#### Person responsible for scientific inquiries

#### Contact

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Arak University of Medical Sciences

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##### Position

faculty member

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Master

**Other areas of specialty/work**

Nursery

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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