

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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)

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+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/m² 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 شیرودی - خیابان علم الهدی

City

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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

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اراک، میدان بسیج، جنب دانشکده پزشکی

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak 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

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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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