Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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/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
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

City
Arak

Province
Markazi

Postal code
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

City
Arak

Province
Markazi

Postal code
۳۸۱۹۶۹۳۳۴۵

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

Street address
Arak University of medical science, Basij Square, Arak,

City
Arak

Province
Markazi

Postal code
۳۸۱۹۶۹۳۳۴۵

Phone
+98 86 3383 8229

Email
farahani.z201625@gmail.com

Person responsible for scientific 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

Street address

Arak university of medical science, Basij Square, Arak,

City

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۶۵

Phone

+98 86 3383 8229

Email

farahani.z201625@gmail.com

Person responsible for updating data

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

Street address

Basij Square

City

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۶۵

Phone

+98 86 3383 8229

Email

farhani.z201625@gmail.com

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