Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of foot reflexology on the pain intensity and frequency of patients with tension headache

Protocol summary

Summary

The purpose of this study was to investigate the effect of foot reflexology on the severity and frequency of tension-type headache patients. This study is a randomized clinical trial study population to patients with neurological centers affiliated to Tehran University of Medical Sciences constitute town. Random sampling is done in two experimental and control groups The study population: 80 patients. Inclusion criteria: tension headaches tend to participate in the study for medical diagnosis according to the patient's medical records. Exclusion criteria: consent to proceed with the project, create or constitute any spatial effects in the patient's legs during the study and completed the maximum two-week diary. In the case of 3-point reflexology foot reflexology including solar network (both feet of floor area, the midpoint of the second and third metatarsal bones connect) the pituitary (SP-1) in the toe of both feet and head (tip all toes) done. 3 minutes on each of these points reflexology done on both feet for a total of about 20 minutes duration.Reflexology massage 2 times a week for 20 minutes per session for 4 weeks has passed by the researcher who conducted the reflexology.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014013016426N1**
Registration date: **2014-11-30, 1393/09/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-11-30, 1393/09/09

Registrant information

Name

Seyed Hossein Vaez Zadeh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Scienes

Expected recruitment start date

2014-10-29, 1393/08/07

Expected recruitment end date

2014-11-28, 1393/09/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology on the pain intensity and frequency of patients with tension headache

Public title

The effect of foot reflexology on the pain intensity and frequency of patients with tension headache

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: willingness to participate in the study; written informed consent to participate in the study; tension headache diagnosis according to the patient's medical records; people with tension headaches have been to the doctor several times over; age over 18 years

old; the ability of listening, speaking, and acceptable alertness for responding; no numbness, or paralysis of leg ulcers; drug and alcohol consumption; no record of having psychological disorders or psychosis; absence epilepsy; lack of cancer, especially lymphoma and nerve damage caused by diabetes; no risk of brain AVM; lack of headache medication escalation. Exclusion criteria: no consent to proceed with the project; create or constitute any kind of side effects in the patient's legs cross over study; acute infectious disease during the study. • Not completing the maximum two-week diary

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical Sciences - Vice Chancellor for Research

Street address
Vice Chancellor for Research, Sixth Floor, Tehran University of Medical Sciences, Qods st., Tehran

City
Tehran

Postal code

Approval date
2014-10-29, 1393/08/07

Ethics committee reference number
1850/130 /93/ص

Health conditions studied

1

Description of health condition studied
Tension headache

ICD-10 code
G44.2

ICD-10 code description
Tension-type headache

Primary outcomes

1

Description
Severity and frequency of pain

Timepoint
Before, during and after intervention

Method of measurement
Headache diary

Secondary outcomes

empty

Intervention groups

1

Description
How do reflexology, in which case the patient lying in the supine position and opposite the clinician and the patient is placed in a quiet environment. Preparations will be carried out before the main technique used to relieve tension and muscle spasms in the body. The toes with one hand and the other hand supporting his fists and feet to the junction of the fingers to the knuckles of the second leg, we massage it down. The medial border of the foot to the big toe side of the wrist to the ankle with a little pressure to make massage (performed three times on each leg).Reflexology in the footsteps of:1-point pituitary, leading the toe of the foot to the point of reflection for the pituitary is rotating clockwise massage for 3 minutes and we left.2. Solar Network: their hands in the shape of a cross. He then places a thumb on the cognitive reflection, as we do in the middle of the foot troughs. Thumbs on the inside leg and three times for 3 min massage is given.3-point reflects the brain: the tip of your toes all within 3 minutes of massage can be arranged at the outside of the thumb. At the last meeting the right and left foot and gently massage to give a blow, and then cover the legs. The patient breathe deeply and say 3 times at the end of the massage, the patient is recommended to drink plenty of fluids this intervention will be done by the researcher who specialized courses reflexology specialist is trained and certified for men and for women by a woman who specialized courses reflexology specialist is trained and certified in the site of clinics and room choice that has already been done.

Category
Other

2

Description
In the control group no intervention will be done. Just

before, during and after the study questionnaires related to the frequency and severity of headaches is completed.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
Seyed Hossein Vaezzdeh

Street address
Imam Khomeini Hospital, Keshavarz Blvd.Tehran

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences - Vice Chancellor for Research

Full name of responsible person
Dr. Masoud Younesian

Street address
Vice Chancellor for Research-Sixth Floor Research-Tehran University of Medical Sciences –qods st-tehran-iran

City
Tehran

Grant name

Grant code / Reference number

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

Title of funding source
Tehran University of Medical Sciences - Vice Chancellor for Research

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Seyed Hossein Vaezzdeh

Position
MSc student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity
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Professor of Nursing

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty