

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The Effect of Foot Reflexology Massage on Reducing Post Dural Puncture Headache

Protocol summary

Study aim

Determining the effect of reflex foot massage on reducing headache caused by spinal anesthesia

Design

The present study will be conducted by the method of randomized controlled clinical trial with the participation of 70 patients undergoing surgery with spinal anesthesia who are suffering from headache. The research samples will be selected by the available method and will be divided into two groups of 35 people, intervention and control, by random allocation with colored cards. This study is one-sided blind and the participants are unaware of the division of groups

Settings and conduct

In the current research, a randomized controlled clinical trial will be conducted, after obtaining ethics approval from the Ethics Committee of the Faculty of Nursing and Midwifery of Shahid Beheshti University of Medical Sciences, and also after completing a reflexology massage training course and receiving approval, the researcher will complete the course. Reflexology massage is done, then the researcher goes to the selected hospitals of Shahid Beheshti University of Medical Sciences. This research will be carried out in a blinded manner so that the patients will be unaware of the grouping of the samples

Participants/Inclusion and exclusion criteria

Inclusion criteria: Being sober, not addicted, having literacy
Exclusion criteria: Having a history of headache, unwillingness to continue participating in the study

Intervention groups

In the intervention group, foot massage will be performed on headache points for 30 minutes (15 minutes for each foot). In the control group, only a simple exfoliation massage will be performed on the soles and feet for 6 minutes (3 minutes each foot)

Main outcome variables

Headache, Systolic and Diastolic Blood Pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230130057284N1**

Registration date: **2023-03-02, 1401/12/11**

Registration timing: **registered_while_recruiting**

Last update: **2023-03-02, 1401/12/11**

Update count: **0**

Registration date

2023-03-02, 1401/12/11

Registrant information

Name

Narges Mahdavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 4224 7692

Email address

narges_mahdavi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Foot Reflexology Massage on Reducing Post Dural Puncture Headache

Public title

The Effect of Foot Reflexology Massage on Reducing Post Dural Puncture Headache

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients between 20 and 60 years of age who undergo surgery using spinal anesthesia Being alert and aware of time and place Being literate in reading and writing Only one attempt has been made to access the subarachnoid space Not receiving painkillers three hours before the intervention Absence of addiction, due to the effect of drugs on the pain tolerance threshold of patients

Exclusion criteria:

Having a history of chronic headache Patients with a history of underlying diseases (having hypertension, neuromuscular diseases) Unwillingness to continue participating in the study Clearance before 24 hours Acute infectious diseases during the study

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method in this study will be available and randomly limited after checking the conditions of entering the study and confirming the presence of headache after spinal anesthesia by a specialist doctor. After determining the final sample size, the samples will be divided into intervention and control groups using random allocation by card lottery. The cards are prepared with the same shape and appearance, and 35 cards with white color will belong to the intervention group and 35 cards with black color will belong to the control group. The cards will be placed in a similar envelope so that the card type is not recognized. An independent research assistant, who will only be involved in randomization, will then draw a card at random

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, participating patients do not know which group they belong to

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Vali Asar Ave

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2022-05-24, 1401/03/03

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1401.046

Health conditions studied**1****Description of health condition studied**

Post Dural Puncture Headache

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Headache Intensity Score

Timepoint

30 minutes of massage in the intervention group for two days immediately and 90 minutes after the intervention

Method of measurement

Visual Analogue Scale

2**Description**

Duration of headache

Timepoint

30 minutes of massage in the intervention group for two days immediately and 90 minutes after the intervention

Method of measurement

Visual Analogue Scale

3**Description**

The amount of housing received

Timepoint

In the entire duration of the intervention

Method of measurement

Housing check list

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, foot massage will be performed on headache points for 30 minutes (15 minutes for each foot). In the control group, only a simple exfoliation massage will be performed on the soles and feet for 6 minutes (3 minutes each foot)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohadaye Tajrish hospital

Full name of responsible person

Maryam Bazgirian

Street address

Tajirish Square

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 25719

Email

sbnmf@sbmu.ac.ir

2

Recruitment center

Name of recruitment center

Imam Hosein hospital

Full name of responsible person

Maryam Tajoddin

Street address

Imam Hossein Square, Shahid Madani Street

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 3000

Email

sbnmf@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahnaz Ilkhani

Street address

Vali Asar Ave

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5363

Email

sbnmf@sbmu.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Narges Mahdavi

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Alzahra girls dormitory, Vali Asar Ave

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

narges_mahdavi@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mahnaz Ilkhani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Vali Asar Ave

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

m_ilkhani@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Narges Mahdavi

Position

Masters Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Alzahra girls dormitory, Vali Asar Ave

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

narges_mahdavi@sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

After the collection and statistical analysis, all the variables in the research can be shared and the personal information of the participants is confidential

When the data will become available and for how long

Probably the end of the year 2023

To whom data/document is available

University researchers, university professors and nursing students

Under which criteria data/document could be used

If the principles of research ethics have been observed and proceeded according to the principles

From where data/document is obtainable

Email: narges_mahdavi@sbmu.ac.ir Narges Mahdavi contact number 00989368347114 Email: m_ilkhani@sbmu.ac.ir Dr. Mahnaz Ilkhani contact number 00989123131526

What processes are involved for a request to access data/document

In this research, sampling takes about 2 months, after that one month is considered for statistical analysis and then the writing of the article begins. In total, this collection takes about 6 to 8 months

Comments