

# 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**

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**Province**

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**Postal code**

1985717443

**Phone**

+98 21 8865 5366

**Email**

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## 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**