

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The Effect of Foot Reflexology Massage on Pain, Anxiety & Physiological parameters in Patients Undergoing Tibia Plaque Surgery

Protocol summary

Study aim

The Effect of Foot Reflexology Massage on Pain, Anxiety & Physiological parameters in Patients Undergoing Tibia Plaque Surgery In Imam Ali (AS) Educational Hospital in Bojnourd in 2020

Design

Clinical trial with control group, with parallel, two-way blind groups, randomized on 96 patients. Block randomized randomized method was used for randomization.

Settings and conduct

This study is performed in Imam Ali Hospital in Bojnourd to evaluate the effectiveness of foot reflex massage on pain, anxiety and physiological indicators of patients under tibial plaque surgery. In this study, 96 patients were randomly assigned to two groups of intervention and control. The test group receives the intervention for 10 minutes and about 2 hours before surgery. The variables studied are measured at specific intervals. None of the patients participating in the study, as well as the person evaluating the outcome and the person analyzing the data, are aware of the study groups.

Participants/Inclusion and exclusion criteria

Entry requirements: Having a healthy limb in the area of the healthy sole of the foot and toes, At least 3 hours have passed since receiving the last analgesic, Absence of fractures in other areas of the patient's body, receiving general anesthesia and patient satisfaction. Conditions of non-entry: Suffering from motor sensory disorders, Vascular diseases, Inflammation and diabetes, history of massage, drug and alcohol addiction, chronic pain such as migraine, history of anti-anxiety drugs, patient dissatisfaction

Intervention groups

There are two groups in this study. The test group receives the intervention as a reflex massage of the sole of the foot for 10 minutes. The massage control group does not receive.

Main outcome variables

Postoperative pain; Anxiety; Physiological indicators (systolic blood pressure, diastolic blood pressure and heart rate)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200502047265N1**

Registration date: **2020-06-30, 1399/04/10**

Registration timing: **retrospective**

Last update: **2020-06-30, 1399/04/10**

Update count: **0**

Registration date

2020-06-30, 1399/04/10

Registrant information

Name

Fateme Imani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3224 6834

Email address

fateme.imany@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-29, 1399/02/10

Expected recruitment end date

2020-06-30, 1399/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Foot Reflexology Massage on Pain, Anxiety & Physiological parameters in Patients Undergoing Tibia Plaque Surgery

Public title
The Effect of Foot Reflexology Massage on Pain, Anxiety & Physiological parameters in Patients Undergoing Tibia Plaque Surgery

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Having a healthy limb in a healthy sole of the foot and toes Spend at least 3 hours receiving the last analgesic No fractures in other areas of the patient's body Get general anesthesia Patient satisfaction
Exclusion criteria:
 Sensory motor disorders Having vascular disease History of massage Suffering from inflammatory diseases and diabetes Drug and alcohol addiction Chronic pain such as migraines History of anti-anxiety drugs Dissatisfaction of patients

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
96 Patients referred to Imam Ali Hospital (AS) who are candidates for Tibial Plaque surgery and other criteria for entering the study, They will be selected as available samples. They will then be randomly assigned to two groups of 48 test and control. Patient allocation in two intervention groups and control group using the method randomly blocked four AACC blocks will be. 24 Blocks were randomly selected and the patients' entry numbers were determined sequentially and placed on the envelope. The type of intervention is done inside the envelope and when the type of intervention is referred. (The letter A indicates the test person and the C letter indicates the control person)

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants who entered the study with satisfaction do not know which group they belong to. The outcome

assessor also does not know which group the patient belongs to. Only the intervener knows the groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics Committee of Mazandaran University of Medical Sciences
Street address
 Mazandaran University of Medical Sciences.Vali-e-Asr Highway,Three ways Joybar,Imam Khomeini Square.
City
 Sari
Province
 Mazandaran
Postal code
 48157-33971
Approval date
 2020-04-29, 1399/02/10
Ethics committee reference number
 IR.MAZUMS.REC.1399.110

Health conditions studied

1

Description of health condition studied
Fracture of the tibia, which requires plaque surgery.

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain score Based on scale (VAS)

Timepoint
Beginning of study; 1 hour after the intervention and in the hours of 2, 4, 6, 12 and 24 hours after the surgery

Method of measurement
Visual Analog Scale(VAS).

Secondary outcomes

1

Description
Anxiety score based on Spiel Berger's questionnaire

Timepoint

At the beginning of the study and 24 hours after surgery

Method of measurement

Spiel Berger's Anxiety Questionnaire

Intervention groups**1****Description**

Intervention group: In this group using baby oil that has no therapeutic value For ten minutes, reflexive foot massage is performed on patients' healthy feet

Category

Treatment - Other

2**Description**

Control group: The researcher lubricates the healthy foot for a minute without any pressure, using baby oil that has no therapeutic value, to eliminate the effect of touch alone. The researcher stayed with the patient for a total of 10 minutes so that the effect of the presence of the massager was equal for both groups.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Ali Hospital in Bojnourd

Full name of responsible person

fateme Imani

Street address

Shahriar Street, Imam Ali Hospital.

City

Bojnourd

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North Khorasan

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9417787885

Phone

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Email

fateme.imany@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

Street address

Central Headquarters of Mazandaran University of Medical Sciences, Vali Asr Highway, Seh Rah Joybar,

Imam Square

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4815733971

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publicrel@mazums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Fateme Imani

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Others

Street address

No. 17, Yasin 6 Street, Shargh Sepah,

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Fateme Imani

Position

University student

Latest degree

Bachelor

Other areas of specialty/work

Others

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Person responsible for updating data**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Fateme Imani

Position

University student

Latest degree

Bachelor