Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 forTibial 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.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Majid Saeedi
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Central Headquarters of Mazandaran University of Medical Sciences, Vali Asr Highway, Seh Rah Joybar, Imam Square
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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
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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