

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of foot massage on sleep quality, severity of pain, and anxiety in patients with tibial fracture repaired by surgery in Khatam Alnabiah Hospital, Zahedan, 2017

Protocol summary

Summary

Every year, millions of people around the world undergo surgery for various reasons. Such actions cause severe and severe pain in the patient and also affect the quality of sleep and the amount of anxiety in the patient. Pain relief, in addition to increasing patient satisfaction, promotes healing faster and has a positive effect on the function of the cardiovascular system. It promotes quality of sleep. There are various ways to control pain, anxiety, and quiet sleep after surgery, including the use of systemic treatments (opiates and non-prescription drugs), and the use of complementary and alternative therapies. One massage therapy. From the branches of complementary medicine, by doing massage of the pituitary glands and hypothalamuses are irritated and secrete endorphin, an endogenous drug similar to morphine. As a result, these neurotransmitters reduce pain and relaxation in the individual. There are doubts about the effectiveness of complementary medicine in the medical community, one of the main challenges of entry. These measures are a set of maintenance functions, which necessitates the existence of a rich research support for the rapid entry of this category into interventions. Due to the lack of a study to determine the effect of foot massage on pain and anxiety and quality of sleep in patients Tummy leg surgery Intervention for one occasion, massage in the foot area (all parts of the foot, leg, heel and toes) from the heel to the fingertips for 5 minutes per foot, for a total of 10 minutes with Use of sweet almond oil, which is one of the most commonly used oils in massage therapy. Foot massage will be performed on the second day after surgery (20 hours after surgery) with the permission of the doctor who is trained by the trained researcher. Objectives: 1- Determine and compare the difference in mean score of sleep quality between the two groups Intervention and control) before intervention and night after intervention

2. Determination and comparison of the difference between mean sleep quality score before intervention and night after intervention in the intervention and control group 3- Determination and comparison of the difference between the mean score of pain between the two Group (intervention and control) before intervention and after intervention. 4- Determination and comparison of the mean score of pain before and after intervention. A and two hours after the intervention in the intervention and control group. 5. Determination and comparison of the mean score of anxiety between the two groups (intervention and control) before and after the intervention. 6. Determination and comparison of the mean of anxiety score before Intervention and immediately after intervention in the intervention and control group. In the intervention and control group, the quality of sleep, pain intensity and anxiety were measured and recorded using the McGill Pain Visual Scale and Spielberger Anxiety Inventory and Pittsburgh Sleep Quality Standard Questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017073135414N1**

Registration date: **2017-08-20, 1396/05/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-20, 1396/05/29

Registrant information

Name

Fatemeh Rezaei Kahkhae

Name of organization / entity

Shiraz university of medical sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Shiraz University of Medical Sciences, Vice Chancellor for Research

Expected recruitment start date
2017-08-03, 1396/05/12

Expected recruitment end date
2017-11-03, 1396/08/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of foot massage on sleep quality, severity of pain, and anxiety in patients with tibial fracture repaired by surgery in Khatam Alnabiah Hospital, Zahedan, 2017

Public title
The effect of foot massage on sleep quality, severity of pain, and anxiety in patients with tibial fracture repaired by surgery

Purpose
Diagnostic

Inclusion/Exclusion criteria
Criteria for entering the study: men and women between the ages of 18 and older; patient undergoing internal fixation (internal fixation) of bone marrow; apply for at least 1 day later surgery in the orthopedic surgery department; awareness of place, person and time; passed at least three hours after the last injection of injectable medicine. Exclusion criteria: Reduced level of consciousness; chronic and malignant pain; drug and alcohol abuse over the past two months; diabetes mellitus more than 10 years; history of neurological, cerebrovascular, psychiatric, respiratory disorders.

Age
From **18 years** old to **99 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz Zand Avenue - Central Building of the University of Medical Sciences

City

Shiraz

Postal code

1978-71345

Approval date

2017-07-09, 1396/04/18

Ethics committee reference number

IR.SUMS.REC.1396.70

Health conditions studied

1

Description of health condition studied

Sleep quality

ICD-10 code

G47.0

ICD-10 code description

G47.0

2

Description of health condition studied

Severity of pain

ICD-10 code

M79.6

ICD-10 code description

M79.6

3

Description of health condition studied

Situational anxiety

ICD-10 code

F41.1

ICD-10 code description

F41.1

Primary outcomes

1

Description

Sleep quality

Timepoint

The morning before and after the intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

2

Description

severity of pain

Timepoint

Before the intervention, half an hour and two hours after the intervention

Method of measurement

MacGill's Painful Visual Scale

3

Description

Anxiety

Timepoint

Before the intervention and immediately after the intervention

Method of measurement

Spillberger's Situational Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, the type of intervention is foot massage. Intervention for one occasion, massage in the foot area (all parts of the foot, leg, heel and toes) from the heel to the fingertips for 5 minutes per foot, for a total of 10 minutes with Use of sweet almond oil, which is one of the most commonly used oils in massage therapy.

Category

Other

2

Description

There is no specific intervention in the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Alnabiah Hospital, Zahedan

Full name of responsible person

Fateme Sargazi

Street address

Jam E jam Boulevard

City

zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology of Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Basir Hashemi

Street address

Shiraz University of Medical Sciences, Zand street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research and Technology of Shiraz University of Medical Sciences

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

Orthopedic section

Full name of responsible person

Fateme Sargazi

Position

Bachelor-nurse

Other areas of specialty/work

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Khatam Alnabiah Hospital

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Niloofer Pasyar

Position

Assistant Professor

Other areas of specialty/work**Street address**

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Npasyar@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz Medical Science Organization

Full name of responsible person

Dr. Nilufar Pasyar

Position

Bachelor

Other areas of specialty/work**Street address**

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Fax**Email****Web page address**

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