Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of foot massage on sleep quality, severity of pain, and anxiety in patients with tibial fracture repaired by surgery in Khatam Alnabia 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 e Ypotalamuses 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

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Name of organization / entity

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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 Alnabia 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 Alnabia 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 Alnabia Hospital
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zahedan
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Niloofar Pasyar
Position
Assistant Professor
Other areas of specialty/work
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Postal code
1978-71345
Phone
+98 71 3647 4254
Fax
Email
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
Shiraz-Zand street
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1978-71345
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Fax
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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