

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of foot reflexology massage on pain intensity and limb movement in patients with operated femur fracture

Protocol summary

Study aim

Determining the effect of reflexology foot massage on pain intensity and limb movement in patients with operated femur fracture

Design

Clinical trial with control group, with parallel groups, randomly controlled, double-blind on 112 patients

Settings and conduct

The study in the orthopedic ward of Shahid Bahonar Hospital is performed on all patients with operated femur fracture. The intervention is performed by massage for 15 minutes, 6 hours after the operation and 12 hours after the first intervention. Before the intervention, Immediately after the intervention and 2, 4, 6, 12 hours later and on the day after the operation and the day of discharge, the amount of pain and movement of the patients' limbs is measured.

Participants/Inclusion and exclusion criteria

Conscious written and oral consent With closed femoral fracture Spinal anesthesia surgery Age 75-18 years At least six hours after surgery Awareness of place, time and person Enjoy complete health of sight and hearing Refer the patient to another medical center Early clearance Consumer of alcohol and other drugs History of similar intervention at least three months ago Wounds, fractures, deformities and skin disorders in the foot

Intervention groups

Intervention group: Massage protocol is performed on a healthy foot for 15 minutes, 6 hours after the operation and 12 hours after the first intervention. Control group: Lubrication of the foot without applying pressure for one minute ,6 hours after the operation and 12 hours after It is done from the first intervention.

Main outcome variables

Pain intensity; limb movement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210725051985N1**

Registration date: **2021-08-16, 1400/05/25**

Registration timing: **prospective**

Last update: **2021-08-16, 1400/05/25**

Update count: **0**

Registration date

2021-08-16, 1400/05/25

Registrant information

Name

Yasaman Ghasempour Soleimani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3214 2397

Email address

yghasempour98@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-22, 1400/05/31

Expected recruitment end date

2021-12-21, 1400/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot reflexology massage on pain intensity and limb movement in patients with operated femur fracture

Public title

The effect of foot reflexology massage on patients after femur surgery

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Conscious written and oral consent With closed femoral fracture Spinal anesthesia surgery Age 75-18 years At least six hours after surgery Awareness of place, time and person Enjoy complete health of sight and hearing

Exclusion criteria:

Refer the patient to another medical center Early clearance Consumer of alcohol and other drugs History of similar intervention at least three months ago Wounds, fractures, deformities and skin disorders in the foot

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be done in the intervention and control group using Envelope Cards. According to the researcher, a number of envelopes containing cards are considered as the intervention group and the same number of envelopes containing cards for the control group; Then, by merging the cards together, a card is taken out and its allocation is recorded, and that card is returned to the group of other cards after being taken out. The cards are then merged again and another card is removed. This process continues until a random sequence according to the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

Evaluation using visual acuity instrument (VAS) immediately and at 2, 4, 6, 12 hours after the first intervention and immediately and at 2, 4, 6, 12 hours after the second intervention until the postoperative day visit by the evaluator colleague The blind is done. The treating physician and physiotherapist (blind) will evaluate the patient's cooperation in moving the operated leg, which is related to the amount of movement, on the day after the operation and on the day of discharge, based on the limb movement evaluation checklist. In order to establish the blinding of the study, by providing the necessary explanations and relevant reasons, patients are asked not to inform anyone else about the intervention without consulting the researcher. And the statistics analyst is also blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Hormozgan University of Medical Sciences

Street address

Vice-chancellor for research, East side of the hospital, Shahid Mohammadi Hospital, Jomhouri Eslami Blv, Bandar Abbas, Hormozgan, Iran

City

Bandarabbas

Province

Hormozgan

Postal code

7916613885

Approval date

2021-07-23, 1400/05/01

Ethics committee reference number

IR.HUMS.REC.1400.163

Health conditions studied**1****Description of health condition studied**

Closed fracture of the femur

ICD-10 code

S72.3

ICD-10 code description

Fracture of femur

2**Description of health condition studied**

Patients' pain after femur surgery

ICD-10 code

G89.18

ICD-10 code description

acute postprocedural pain

3**Description of health condition studied**

Movement of patients' limbs after femur surgery

ICD-10 code**ICD-10 code description****Primary outcomes**

1

Description

Visual Analog Scale (VAS) Patient Pain Score

Timepoint

immediately at 2, 4, 6, 12 hours after the first intervention and immediately at 2, 4, 6, 12 hours after the second intervention until the day after surgery

Method of measurement

This scale is a horizontal ruler that is divided from zero to 10 and measures the severity of pain. The amount of pain is measured by the researcher using the Visual-Linear Pain Scale (VAS), which is standardized for measuring pain. The Linear-Visual Pain Scale is divided from zero to ten as follows: 1-3 Mild pain 4-7 moderate pain 8-10 Severe pain The number zero means painless and the number 10 means very severe pain.

2

Description

Rank the amount of member movement based on the checklist

Timepoint

The day after surgery and the day of patient discharge

Method of measurement

In this checklist, questions related to moving the operated organ of the patient based on the comments and examination and observation of the treating physician and physiotherapist on the day after surgery and the day of discharge in the field of pain-relaxation-movement and patient cooperation as six options from No cooperation until very well described by the sign.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the intervention group will receive a foot reflexology massage. In this study, the researcher will place the patient in a comfortable supine position. Disinfecting and washing the feet will be done at the beginning and at the end of the work. For 15 minutes, the healthy foot will be subjected to a reflexology massage technique using baby oil, which has no therapeutic value. The researcher will sit on a chair at the bottom of the patient's bed and massage as follows: and first the soles of the feet will be gently massaged, gentle movements and gentle massage will take 1 minute from the beginning and 1 minute from the last minutes of the massage. First, in a healthy foot, according to the foot massage reflection massage protocol, some of the first ten treatment techniques in this type of massage, which is a multiple of three, will be performed. And then we will do the same stimulation and stabilization techniques in the same way. The three sensitive points, which are the solar plexus, the pituitary gland and the heart, will be under constant pressure for

2 minutes (at any point) with the thumb. The pressure is such that the upper third of the researcher's thumb turns white and the patient feels this pressure but does not feel pain. These points will first be pressed steadily for two minutes and then massaged in a circular motion. The purpose of the massage is to move the thumbs in a circular motion in a clockwise direction and continuously on the reflection points without losing contact with the skin. This technique will be done the same for all patients and also the reflex massage of the sole of the foot for women. It will be done by the researcher and for men under the direct supervision of the researcher and by a trained male research colleague.

Category

Rehabilitation

2

Description

Control group: In this group, the trained researcher and colleague place the patients in a comfortable supine position. 6 hours after the surgery and also 12 hours after the first intervention, they lubricate the foot for one minute without any pressure to achieve the effect of touch. The dependent variable (pain) should be the same in both groups and controlled. They will also stay with the patient for 15 minutes to ensure that the effect of the presence of a massager is the same for both groups (14). The measurement of the patient's pain intensity in the same hours as the intervention group is done by a blind assessor and movement evaluation is done by the treating physician and physiotherapist in this group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Bahonar Educational and Medical Center

Full name of responsible person

Mehdi Ahmadinezhad

Street address

Gharani Street., Shahid Bahonar Hospital

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Fax

+98 34 3226 0100

Email

mehdia50@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Teamur Aghamolaei

Street address

Vice-chancellor for research, East side of the hospital,
Shahid Mohammadi Hospital, Jomhouri Eslami Blv,
Bandar Abbas, Hormozgan, Iran

City

Bandarabbas

Province

Hormozgan

Postal code

7916613885

Phone

+98 76 3333 8583

Email

taghamolaei@hums.ac.ir

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

Yes

Title of funding source

Bandare-abbas 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**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Yasaman Ghasempour Soleimani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Gharani Street., Shahid Bahonar Hospital

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

yghasempour98@gmail.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Hadi Yousefi

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

Street address

Emam Hosein Blvd., University of Medical Sciences

City

Bandarabbas

Province

Hormozgan

Postal code

7916613885

Phone

+98 76 3331 7723

Email

hadiyousefi17@gmail.com

Person responsible for updating data

Contact**Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Yasaman Ghasempour Soleimani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Gharani Street., Shahid Bahonar Hospital

City

Kerman

Province

Kerman

Postal code

7613747181

Phone

+98 34 3223 5011

Email

yghasempour98@gmail.com

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 more 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