

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study of the effect of gentle stretching exercises and foot reflexology massage on the pain of patients after spinal surgery

Protocol summary

Study of the severity of pain in the lower limbs and the back in patients ,after spinal surgery

Study aim

Effect of gentle exercises and foot reflexology massage on pain after spinal surgery

Design

This study was a randomized clinical trial with a control group with parallel, one-blind, randomized groups. Patients were entered on the basis of inclusion criteria and are randomly assigned to the control or intervention group 1 and 2 using closed envelopes

Settings and conduct

Patients undergoing thoracic and lumbar spine surgery according to entry criteria are randomly divided into two intervention groups and one control group. The day before surgery, the demographic and medical characteristics of the patient were completed and pain intensity was recorded using the visual scale of the pain. Intervention in group 1 on the day after surgery is reflexology massage of the foot of the foot that continues after discharge three times a week for 6 weeks. In group 2, tensile training begins on the day after surgery, which is performed in the lining or sitting room for half an hour during the hospitalization period and 3 times a week for 6 weeks in the discharge period. In the control group, only routine medications and care are performed. The severity of pain in patients was measured and recorded in all three groups before surgery, the first day after surgery, discharge time and then one week and six weeks later using the visual scale.

Participants/Inclusion and exclusion criteria

-Aged 65-18 years old - Complete lack of sensory and motor impairment in the lower extremities - Nervous musculoskeletal disorders - No scarring, fractures and skin disorders in the legs - No alcohol and other drugs - No limitation of movement in the foot - Failure to develop malignant diseases

Intervention groups

Group 1: Soft stretching exercises Group 2: Foot reflexology

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180404039194N1**

Registration date: **2018-08-19, 1397/05/28**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-19, 1397/05/28**

Update count: **0**

Registration date

2018-08-19, 1397/05/28

Registrant information

Name

Ommolbanin Rostami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3341 9914

Email address

rostamio1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of gentle stretching exercises and foot reflexology massage on the pain of patients after spinal surgery

Public title

Study of the effect of gentle stretching exercises and foot reflexology massage on the pain of patients after spinal surgery

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with thoracic and lumbar spine surgery
Complete lack of sensory and motor impairment in the lower extremities of patients who have had spine surgery
Satisfaction with co-operation during admission and continuation at home
Lack of inflammatory and vascular diseases, such as arthritis and vascular thrombosis
Absence of musculoskeletal disorders
Lack of ulcers, fractures and skin disorders in the legs
Lack of alcohol and other drugs
Lack of limb movement in the lower extremity
Not pregnant
Non-malignant diseases
Being trained or accompanying
Age of 16-70 years

Exclusion criteria:

Lack of spinal surgery
Sensory and motor disorder, complete or incomplete in lower limbs
Any wounds in the foot
Incompetent the patient or accompany of her or him

Age

From **16 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Assigned with random spss numbers, in intervention or control groups, randomly

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients who have spinal surgery have undergone surgery or intervention according to entry criteria and randomly in the control group or intervention group 1 or 2. Patients in each group are unaware of being in the intervention or control group. However, in each group patients are told about routine or intervention (reflexology or stretching exercises) and they will intervene in case of written consent.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

regional research ethics committee Mashhad
University of Medical Sciences

Street address

Medical-Surgical Department, Nursing and Midwifery
School, Ebnesina Street, Doctra Crossroad, Mashhad,
Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2018-06-30, 1397/04/09

Ethics committee reference number

IR.MUMS.REC.1397.084

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

Severity of pain after surgery of the thoracic sphincter
and lumbar spine

ICD-10 code

G54

ICD-10 code description

Nerve root and plexus disorders

Primary outcomes**1****Description**

Severity of pain after surgery of the thoracic sphincter
and lumbar spine

Timepoint

Measuring the severity of pain in patients using the
visual scale of pain in the day before surgery, the day
after surgery, one week and 6 weeks after surgery in
person or through telephone follow up or patient referral
to the clinic of the studied hospitals

Method of measurement

Measuring the pain intensity of patients using the visual
scale of pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: The intervention is performed as a reflexology massage on the sole of the palm, with the thumb, on the inner curvature of the floor of both legs, the alternating to the wave and smoke, and in the reciprocation of about 10 -7 minutes per foot. This intervention is performed at least once a day, 3 times a week and for 6 weeks.

Category

Rehabilitation

2

Description

Intervention group:

Category

Rehabilitation

3

Description

Control group:

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Emdadi Shahid Kamyab hospital, Ghaem hospital, Hasheminejad hospital

Full name of responsible person

Mahmood Bakhshi

Street address

Emdadi Hospital, Fadaeiyan Eslam Street, Nakhrisi Intersection

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<http://h-kamyab.mums.ac.ir/>

2

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Bakhshi Mahmood

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Qa'im Hospital, Dr Ali Shariati Square, Beginning at Ahmadabad Street

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Recruitment center

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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Faculty of Nursing and Midwifery, Ebne Sina Ave., Duktora Intersection, Mashhad, Iran

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

Yes

Title of funding source

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Ommolbanin Rostami

Position

Senior of Surgical Medical Nursing Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

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Position

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

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Position

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Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The effect of mild stretching exercises and foot reflexology massage on the severity of pain in the lower and lower extremities in patients undergoing thoracic and lumbar spine surgery. The results of this research are shared among other researchers in this regard.

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Researchers and patients candidate for spinal surgery

Under which criteria data/document could be used

Data analysis will be done using descriptive and inferential statistics. After collecting data and encoding and logging into the computer, spss 11 will be used for analysis. To describe the data, the frequency distribution

table (for qualitative variables) and the mean and standard deviation (for quantitative variables) will be used. In the analytical statistics, first, a quantitative quantitative test of normal values using Kolmogorov-Smynov and Shapiro Wilk tests. To determine the homogeneity of data in three groups, the Chi-square or Fisher test for qualitative variables and the Kruskal-Wallis test will be used for quantitative variables in case of normalization. Also, intra-group comparisons will be used based on whether data are normal or not. Friedman test variance analysis will be used. To determine the relationship between underlying and intervention variables, three groups of two-way ANOVA tests will be used. For all tests, the confidence coefficient will be 95%.

From where data/document is obtainable

Faculty of Nursing and Midwifery, Ibn Sina Avenue, Doktora st. Mashhad, Iran Phone: 0098 5138591511 Fax: 0098 5138597313 Zip Code: 9137913199 E-mail: NMS.IT@mums.ac.ir

What processes are involved for a request to access data/document

Referring to the library of Mashhad Nursing and Midwifery Faculty and presenting the identification card to this unit and receiving the existing documentation.

Comments