Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of foot reflexology massage on pain and fatigue after lumbar spine surgery

Protocol summary

Study aim

 Determining the effect of foot reflexology massage on pain and fatigue after lumbar spine surgery in patients admitted

Design

This interventional study is a randomized, clinical trial with two intervention and control groups. The data gathering tool was a demographic questionnaire and a visual analogue scale for measuring pain and fatigue in patients (from zero to 10.

Settings and conduct

After obtaining the ethics committee, the researcher visits Shaheed Beheshti Hospital. Based on the criteria for entry, the patients are divided into two groups of test and control according to the list drawn from the random numbers table, which is covered by the patient.

Participants/Inclusion and exclusion criteria

1. At least 3 months of back pain before surgery 2. Be alert at the time of research 3. Age between 35 and 60 years 4. Spinal cord stenosis in the lumbar region with moderate severity 5. Body Mass Index (BMI) Between 5/16 to 30

Intervention groups

The demographic questionnaire is completed and the severity of pain and fatigue and physiological indicators are immediately measured and recorded before intervention. Then, in the test group, the foot reflexology massage nurse after washing and greasy hands with olive oil routinely and 5 minutes on pituitary and Solar Plexus points and 10 minutes of lumbar spine points on each of the legs It will take 30 minutes to complete the massage. Immediately after massage, 60 and 90 minutes and 24 hours after massage, the severity of pain and fatigue and physiological indicators are re-measured and recorded. In the control group, after hand-fatting with olive oil, each patient's leg should be fattened at least 5 minutes each time for one minute, with approximately the amount of oil consumed equal to the intervention group.

Main outcome variables

Intensity of pain،Tiredness،Clinical signs of hypertension and respiratory depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181111041608N1**
Registration date: **2018-11-20, 1397/08/29**
Registration timing: **retrospective**

Last update: **2018-11-20, 1397/08/29**
Update count: **0**

Registration date

2018-11-20, 1397/08/29

Registrant information

Name

Maryam Amirpoor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 74 3322 1813

Email address

m.amirpoor@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-22, 1396/05/31

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

2017-08-22, 1396/05/31

Actual recruitment end date

2018-02-19, 1396/11/30

Trial completion date

2018-02-19, 1396/11/30

Scientific title

The effect of foot reflexology massage on pain and fatigue after lumbar spine surgery

Public title

Determining the effect of foot reflexology massage on pain and fatigue after lumbar spine surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

1. At least 3 months of back pain before surgery2. Be alert at the time of research3. Age between 35 and 60 years4. Spinal cord stenosis in the lumbar region with moderate severity5. Body Mass Index (BMI) Between 5/16 to 30

Exclusion criteria:

1. No tolerance 2. Anesthesia in the legs 3. Vascular disorders of the lower limbs 4. Lower limb flexion 5. Drug Addiction and Substance Abuse 6. Get Pain Pump By Self Patient 7. Rupture of Intervertebral Disk 8. Stroke of Spinal Cord

Age

From **35 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **68**

Actual sample size reached: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

After easy sampling of qualified individuals and completion of informed written consent, samples are divided into two groups of test and control according to the list drawn from the random numbers table.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients were divided into two groups of test and control. They were explained to the patients themselves (both groups). Data was collected at all stages by an unknowing nurse of the group.

Placebo

Not used

Assignment

Parallel

Other design features

no

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee in Shahid Sadoughi University of Medical Sciences Yazd

Street address

Yasuj shahid motahari

City

Yasuj

Province

Kohgilouyeh-va-Boyrahmad

Postal code

7591794857

Approval date

2017-03-06, 1395/12/16

Ethics committee reference number

IR.SSU.REC.1395.239

Health conditions studied

1

Description of health condition studied

Spinal Surgery

ICD-10 code

G55.1

ICD-10 code description

G55.1

Primary outcomes

1

Description

PAIN

Timepoint

Post-interventional pain (30 minutes for control group), 60 minutes after intervention, 90 minutes after intervention, 24 hours after intervention

Method of measurement

Standard Scale -New

2

Description

Fatigue

Timepoint

Post-interventional pain (30 minutes for control group), 60 minutes after intervention, 90 minutes after intervention, 24 hours after intervention

Method of measurement

Standard Scale -New

3

Description

Signs of blood pressure and respiratory and pulse

Timepoint

Post-interventional pain (30 minutes for control group),

60 minutes after intervention, 90 minutes after intervention, 24 hours after intervention

Method of measurement

Pulse measurements are measured by touching the pulse position and the counting and inhalation by measuring and observing the pressure measurement device.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, the researcher thoroughly washes his hands with warm water and smears with olive oil and massage together to slip through the warmth of the hands to ease the reflex massage. The patient is placed in the back rest position and, while foot massage, is supported by a pillow below it, and placed higher and removed after the massage of the pillow. After relaxing techniques for 5 minutes, the pituitary reflexes, Solar Plexus points, the spinal reflex points are massage for 10 minutes. The total massage time is 30 minutes (15 minutes each).

Category

Other

2

Description

Control group: In the control group, the researcher at the time corresponding to the test group, twice in 5 minutes intervals, and at least once for a minute, without any compression, lubricates the points on both sides of the patient.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital

Full name of responsible person
Maryam Amirpoor

Street address
Kohgiluyeh and Boyer-Ahmad Province, Yasuj, Montazeri St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr Masoud Mirzaei

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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
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
Maryam Amirpoor

Position
Senior Care Nursing Student

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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Data results are published
When the data will become available and for how long
Three months after completion
To whom data/document is available
For scholars working in academia and academia
Under which criteria data/document could be used
by Email
From where data/document is obtainable
With the author of the article
What processes are involved for a request to access data/document
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