

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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-fattening 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 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
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

Kohgiluyeh-va-Boyerahmad

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

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7591794857

Phone

+98 74 3322 1813

Email

m.amirpoor@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr Masoud Mirzaei

Street address

Yazd Bahonar Square, Shahid Sadoughi University of Medical Sciences and Health Services Yazd, Third Floor

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 35 3149 2248

Email

mmirzaei@ssu.ac.ir

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

Street address

Yasuj Shahid Motahari

City

Yasuj

Province
Kohgiluyeh-va-Boyrahmad
Postal code
7591794857
Phone
+98 74 3322 4721
Email
m.amirpoor@ssu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Dr. Mostafa Javadi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Yazd - Safaiyeh - Bou-Ali Boulevard - Nursing and midwifery department
City
Yazd
Province
Yazd
Postal code
8915173160
Phone
+98 35 1824 1751
Email
javadi@ssu.ac.ir

Person responsible for updating data

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
Street address
motahhari sd.
City
Yasuj
Province
Kohgiluyeh-va-Boyrahmad
Postal code
7591794857
Phone
+98 74 3323 4722
Email
m.amirpoor@ssu.ac.ir

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

It is answered by e-mail as soon as possible

Comments