

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of foot refelxology massage on pain of scoliosis patients undergoing spinal surgery

Protocol summary

Summary

The main objective behind conducting this research is to identify the effect of reflective massage on foot sole of patients suffering from scoliosis and receiving spinal cord surgery. The patients and the evaluator will not be aware of the method for conducting this study. Hence, this study is a double blind, parallel clinical trial. The inclusion criteria include being conscious after surgery, receiving the last analgesic at least four hours ago and being desired too participate in the study. Addiction to drugs, pain relievers and amphetamines, having foot disorders, referring to another hospital and having prior record of vascular, lymphatic and inflammatory diseases will be the exclusion criteria. The sample size will be 56 patients (two groups with 28 subjects in each) who will be randomly assigned to experiment (reflective massage) and control groups. The intervention in the experiment group will be made through gentle massage into foot sole followed by exerting pressure on pituitary, solar plexus, muscular-skeletal system and urinary system for 30 minutes (15 minutes for each foot) once a day from the second until the fifth day after the surgery. In order to counteract the effect of touch and maintain the blinding conditions similar to the experiment group, the feet of subjects in the control group will be anointed for one minute from the second until the fifth days following the surgery. The main variable in this study is pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014093019347N1**

Registration date: **2014-11-30, 1393/09/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-11-30, 1393/09/09

Registrant information

Name

Shima Abedini

Name of organization / entity

Azad University Tehran Medical branch

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Azad University of Tehran, Medical branch

Expected recruitment start date

2013-07-11, 1392/04/20

Expected recruitment end date

2014-01-30, 1392/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot refelxology massage on pain of scoliosis patients undergoing spinal surgery

Public title

The effect of foot reflexology massage on pain

Purpose

Supportive

Inclusion/Exclusion criteria

The inclusion criteria include being conscious after surgery; receiving the last analgesic at least four hours ago and being desired too participate in the study. Addiction to drugs, pain relievers and amphetamines; having foot disorders; referring to another hospital and having prior record of vascular; lymphatic and inflammatory diseases will be the exclusion criteria

Age

From **10 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

With regard to the fact that spinal cord surgery is performed on Saturdays, Mondays, Tuesdays and Wednesdays, the researcher will select two days randomly for the experiment group while the other remaining two days will be allocated to patients in the control group.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Islamic Azad University
Tehran Medical branch

Street address

Gholhak, Khaghani st, Shariati ave, Tehran

City

Tehran

Postal code

1916893813

Approval date

2013-07-10, 1392/04/19

Ethics committee reference number

1023- 92/4

Health conditions studied

1

Description of health condition studied

Scoliosis

ICD-10 code

M41

ICD-10 code description

Scoliosis

Primary outcomes

1

Description

Pain

Timepoint

Before and after 30 minutes

Method of measurement

Short form Macgill pain questionnaire

2

Description

Pain

Timepoint

Every session before intervention and after 30 minute

Method of measurement

Visual analoge scale

Secondary outcomes

1

Description

Pain medication consumption

Timepoint

Every session before intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

"control group: To eliminate the effects of touch and maintain blind conditions similar to the experimental group, on the second to fifth postoperative day, once a day for 1 minute feet were fat"

Category

Placebo

2

Description

"Intervention group: Foot Reflexology massage from the second to the fifth postoperative day, once a day for 30 minutes was performed"

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa Yahyaieian Hospital

Full name of responsible person

Shima Abedini

Street address

Mojahedin st, Mojahedin sq, Tehran

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Islamic Azad University of
Tehran, Medical branch

Full name of responsible person

Dr. Shahabodin Mohseni

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Gholhak, Khaghani st, Shariati ave

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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

Vice chancellor for research, Islamic Azad University of
Tehran, Medical branch

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

Islamic Azad University of Tehran, Medical branch

Full name of responsible person

Shima Abedini

Position

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Other areas of specialty/work

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Person responsible for updating data

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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