

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

The effects of foot reflexology on pain of patients after lower limb amputation.

Protocol summary

Summary

Objective: The aim of this study is to evaluate the effect of foot reflexology on post amputation pain. Design: A randomized clinical trial Setting: This study involved two groups of 50 patients undergoing lower limb amputation will be done. Each group consisted of 25 people. Random allocation of samples will be done using block randomization. Intervention: Foot reflexology will be done for 30 minutes in the intervention group and the control group only foot massage will be done without purpose. Before and after the intervention to assess and compare pain intensity NSR scale is used. Inclusion criteria: included be conscious, lack of mental retardation, Patient satisfaction in participating in the study. Exclusion criteria: included lack of patient cooperation during study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011825929N1**

Registration date: **2016-02-28, 1394/12/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-02-28, 1394/12/09

Registrant information

Name

Mehdi Molavi Vardanjani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3422 5056

Email address

m.molavi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2016-01-30, 1394/11/10

Expected recruitment end date

2016-08-21, 1395/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of foot reflexology on pain of patients after lower limb amputation.

Public title

Effect of foot reflexology on pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Be conscious! Lack of mental retardation! Patient satisfaction in participating in the study. Exclusion criteria: Lack of patient cooperation during study.

Age

From **20 years** old to **45 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Allocation of samples will be done using block randomization.

Secondary Ids

1
Registry name
-
Secondary trial Id
-
Registration date
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Isfahan
City
Isfahan
Postal code
Approval date
2014-11-20, 1393/08/29
Ethics committee reference number
293183

Health conditions studied

1
Description of health condition studied
Injury
ICD-10 code
S88.9
ICD-10 code description
Traumatic amputation of lower leg, level unspecified

Primary outcomes

1
Description
Pain
Timepoint

Before and 30 minutes after intervention
Method of measurement
NSR scale

Secondary outcomes

1
Description
Vital signs
Timepoint
Before and after intervention
Method of measurement
Chek list

Intervention groups

1
Description
In the intervention group, foot reflexology will be performed for thirty minutes. First, the researchers washed their hands with warm water then for thirty minutes to massage the three points of Metatarsus.
Category
Other

2
Description
In the control group only regular foot massage will be performed for thirty minutes.
Category
Treatment - Drugs

Recruitment centers

1
Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Mehdi Molavi Vardanjani
Street address
Isfahan- Keshavarz Bolvar
City
Isfahan

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Vice Chancellor for research of Isfahan University of Medical Sciences
Full name of responsible person
Mohsen Shahriari
Street address
Isfahan

City
Isfahan

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 of Isfahan University of Medical Sciences

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
Isfahan University of Medical Sciences

Full name of responsible person
Mehdi Molavi Vardanjani

Position
Master of Sciences

Other areas of specialty/work

Street address
Isfahan

City
Isfahan

Postal code

Phone
+98 31 3775 6084

Fax

Email
m.molavi@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Isfahan University of Medical Sciences

Full name of responsible person
Mehdi Molavi Vardanjani

Position
Master of Sciences

Other areas of specialty/work

Street address
Isfahan

City
Isfahan

Postal code

Phone
+98 31 3775 6084

Fax

Email
m.molavi@umsha.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
University of Medical Sciences

Full name of responsible person
Mehdi Molavi Vardanjani

Position
Master of Sciences

Other areas of specialty/work

Street address
Isfahan

City
Isfahan

Postal code
8857113317

Phone
+98 31 3775 6084

Fax

Email
m.molavi@umsha.ac.ir

Web page address

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