

# 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*