

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 2026

The effect of vibrating silicone liner on phantom pain in below knee amputees

Protocol summary

Study aim

Design, construct and evaluate vibrating silicon liner on the phantom pain in traumatic below knee amputees

Design

Clinical trial, single group, no control group, not blinded

Settings and conduct

Study on the Red Crescent of Tehran, vibrating silicon liners are built for all people according to their stump structure, each participant using vibrating silicone liner three times per day for 10 minutes and in a period of 30 days, the severity of pain was evaluated by the short form of McGill Pain Questionnaire before and after thirty days using vibrating silicon liner.

Participants/Inclusion and exclusion criteria

Traumatic below knee amputation with phantom pain

Intervention groups

Vibrating Silicon Liner

Main outcome variables

Phantom pain measuring

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140219016643N5**

Registration date: **2019-01-26, 1397/11/06**

Registration timing: **retrospective**

Last update: **2019-01-26, 1397/11/06**

Update count: **0**

Registration date

2019-01-26, 1397/11/06

Registrant information

Name

Behshid Farahmand

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-05-27, 1395/03/07

Expected recruitment end date

2016-12-30, 1395/10/10

Actual recruitment start date

2016-05-27, 1395/03/07

Actual recruitment end date

2017-01-29, 1395/11/10

Trial completion date

2018-08-01, 1397/05/10

Scientific title

The effect of vibrating silicone liner on phantom pain in below knee amputees

Public title

The effect of vibration on the phantom pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Traumatic below knee amputee Phantom pain score 4 or more based on the Visual Analog Scale

Exclusion criteria:

Bilateral amputation Stump length more than 7 inches
Did not use prosthesis Received other medical or non-surgical treatments for phantom pain Suffered from other diseases such as diabetes, joint rheumatoid arthritis, and neuromuscular problems

Age

From **20 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **8**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Mother Square, Abkar Shahnazari Street, Madadkaran Street, Faculty of Rehabilitation Sciences

City

Tehran

Province

Tehran

Postal code

1545913487

Approval date

2016-05-23, 1395/03/03

Ethics committee reference number

IR.IUMS.REC 1395.9221502201

Health conditions studied

1

Description of health condition studied

Below knee amputee with phantom pain

ICD-10 code

G54.6

ICD-10 code description

Phantom limb syndrome with pain

Primary outcomes

1

Description

Phantom pain

Timepoint

Before intervention, immediate after intervention, after 30 days use of vibrating silicone liner

Method of measurement

Short form of McGill Pain Questionnaire

Secondary outcomes

1

Description

Relationship between level of pain and demographic variables such as age, body mass index, Duration of amputation and the level of initial pain

Timepoint

Before intervention, after 30 days use of vibrating silicone liner

Method of measurement

Visual Analog Scale, demographic questionnaire

Intervention groups

1

Description

Vibrating silicon liner: the silicone liner is made of two layers and has an elasticity effect due to the use of socks between layers. The connecting wires of the vibration motors are placed between the two layers of the liner. Vibration motors are placed at the pain location, close to the nerve and peroneal artery and at the end of the stump to stimulate the neural mechanisms and proprioception. The ends of the vibration connections are connected to a socket, where the adapter is installed as a power supply. The power supply consists of an adapter with a maximum voltage of 12V and, due to the low voltage, does not pose any danger to the patient. Vibration is also applied at a frequency of 100 Hz by vibration motors.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Red Crescent Rehabilitation Center

Full name of responsible person

Omid Turkeman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Kazem Malakoti

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Behshid Farahmand

Position

Assistance Professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthotics & Prosthetics

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Person responsible for scientific inquiries

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Position

Assistance Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All study data are shareable after deleting the profile and contact number of the participants

When the data will become available and for how long

The start access is determined according to the law of the journal which the article is submitted

To whom data/document is available

Accessibility for all people

Under which criteria data/document could be used

Do not consider a particular item

From where data/document is obtainable

Contact by e-mail of corresponding author

What processes are involved for a request to access data/document

If there is no precautionary statement from the journal which the article is printed, with contact by e-mail of corresponding author, information will be sent to the requesting person within less than one month

Comments