Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
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Behshid Farahmand
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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

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Full name of responsible person
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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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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
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