Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation the Effect of Medical Insole on Balance in Transtibial Amputees

Protocol summary

Study aim
Investigation of the effect of medical insoles on the balance of unilateral below knee amputees

Design
An intervention study of the before and after type is performed on 10 individuals. Samples will be selected using the available sampling method. Accidentalization and study phase do not apply. The study is not blind.

Settings and conduct
This study is being conducted at Isfahan University of Medical Sciences, School of Rehabilitation, and the Center for Musculoskeletal Research. The information required in this study will be collected by laboratory observations. Data collection tools include: demographic information recording questionnaire and force plate. Individuals will stand on the force plate for one minute during each balance test. Data collection modes include: With insoles and open eyes, without insoles and open eyes, with insoles and closed eyes, without insoles and closed eyes. Each of these tests will be repeated 5 times for each person. So in total we will have 20 times to collect information. Each test has a code. The order of the tests will be random and by removing the codes inside the envelope.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with unilateral below knee amputation Exclusion criteria: healthy or amputated individuals other than under the unilateral below knee

Intervention groups
The intervention group includes 10 people who receive medical insoles and each person's balance is compared to himself or herself before and after using insoles. The insoles for each person will fit the length of his or her foot inside the standard shoe according to the prosthesis material. In order to compensate for the difference in length due to the insole, a heel lift with the same material as ethylene vinyl acetate is used on the prosthetic side.

Main outcome variables
Balance of below knee amputee

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181113041636N3**
Registration date: **2020-05-13, 1399/02/24**
Registration timing: **prospective**

Last update: **2020-05-13, 1399/02/24**
Update count: **0**

Registration date
2020-05-13, 1399/02/24

Registrant information

Name
tahmoures tahmsebi notoraki

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 3792 5015

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-21, 1399/03/01

Expected recruitment end date
2020-05-30, 1399/03/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation the Effect of Medical Insole on Balance in Transtibial Amputees

Public title
Evaluation the Effect of Medical Insole on Balance in Transtibial Amputees

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Uilateral below knee amputees Use a prosthesis for at least 6 hours during the day The length of the stump should be between 5 and 7 inches Amputation due to trauma Have at least one year of prosthetic use Use a SACH prosthetic foot

Exclusion criteria:
Bilateral amputation Partial Foot, Knee or Above Knee Amputation Having musculoskeletal and cardio-respiratory problems Use aids such as a cane to walk Use lower limb orthoses on the intact side Stump-related problems include cracked skin, sores, bruises and blisters Amputation due to vascular disease People with foot supination Having vision and vestibular problems Having central neurological problems

Age
From **20 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **10**

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
Ethics committee of Esfahan University of Medical Sciences

Street address
Esfahan University of Medical Sciences, Azadi Square, Hezar Jarib Street

City
Esfahan

Province
Isfehan

Postal code
8174673461

Approval date
2018-06-20, 1397/03/30

Ethics committee reference number
IR.MUI.RESEARCH.REC

Health conditions studied

1

Description of health condition studied
Balance in unilateral trans-tibial amputee people

ICD-10 code
S88

ICD-10 code description
Traumatic amputation of lower leg

Primary outcomes

1

Description
Static Balance

Timepoint
Balance measurement using medical insole and without the use of medical insole

Method of measurement
Force plate

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For this group, use full-length insoles made of ethylene vanilla acetate (EVA) with medium hardness, with medial longitudinal arch support and Heel Cup and metatarsal pad. These insoles fit the length of the person's foot and inside the standard shoe according to the prosthesis material.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Musculoskeletal Research Center

Full name of responsible person
Tahmores Tahmasbi
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Faculty of Rehabilitation, West Door of Isfahan University of Medical Sciences, Sofeh Blvd.
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Tahmoures Tahmasebi
Position
Faculty member
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Person responsible for updating data

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available