

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 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)

Phone

+98 31 3792 5015

Email address

t_tahmasbi@yahoo.com

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:
Unilateral 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
Isfahan
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

Tahmoures Tahmasbi

Street address

Faculty of Rehabilitation, West Door of Isfahan
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Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Tahmoures Tahmasebi

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Orthotics and Prosthetics

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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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 scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Tahmoures Tahmasebi

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Tahmoures Tahmasebi

Position**Person responsible for general inquiries****Contact**

Faculty member

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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