

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

The effect of the lateral wedge on the knee adduction moment in the sound side of unilateral Trans-Tibial amputees

Protocol summary

Study aim

Determining the effect of medical insoles with lateral wedges on the knee adduction moment on the intact side of people with unilateral below-knee amputation.

Design

An intervention study of the before and after the type is performed on 10 individuals. Samples will be selected using the available sampling method from among those who refer to technical orthopedic centers.

Settings and conduct

This study will be conducted at Isfahan University of Medical Sciences, Faculty of Rehabilitation, Musculoskeletal Research Center. The information required in this study will be collected through laboratory observations. Data collection tools include demographic information recording questionnaire and force plate device. Participants will walk on a 5-meter-long force plate to perform the test once with a medical insole with a lateral wedge and once without a medical insole. To reduce the measurement error, each test will be repeated 5 times. The sequence of tests will be random.

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 the knee.

Intervention groups

The intervention group will include 10 people who will receive a medical insole with a lateral wedge. knee adduction moment in the intact side will be compared to before and after using the insole.

Main outcome variables

Knee adduction moment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181113041636N2**

Registration date: **2020-05-10, 1399/02/21**

Registration timing: **prospective**

Last update: **2020-05-10, 1399/02/21**

Update count: **0**

Registration date

2020-05-10, 1399/02/21

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

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the lateral wedge on the knee adduction moment in the sound side of unilateral Trans-Tibial amputees

Public title

The effect of the lateral wedge on the knee adduction moment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The amputation of the lower limb is below the knee and unilateral. The minimum time to use a prosthesis during the day is 6 hours. Stump length is normal and natural. Amputation due to trauma. Be at least 30 years old. Have at least 10 years of prosthetic use. Use on SACH prosthetic foot.

Exclusion criteria:

Grade 3 and 4 osteoarthritis of the knee. Partial foot, knee disarticulation, above knee amputation. Bilateral amputation. Problems in neuromusculoskeletal, psychology and respiratory cardiac. Using from the cane. Use of lower limb orthotics. Problems in the skin of the stump. Amputation due to Vascular Disease. Having foot supination. Having foot pronation. Having a Knock-knee in intact side. Muscle contracture in intact side. Having the vision and vestibular problems.

Age

From **30 years** old to **70 years** old

Gender

Male

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 Isfahan University of Medical Sciences

Street address

Hezarjerib St ., Azadi Sq ., Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-12-13, 1398/09/22

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.517

Health conditions studied

1

Description of health condition studied

Osteoarthritis in the sound limb of the knee of unilateral trans-tibial amputee people.

ICD-10 code

M17.5

ICD-10 code description

Other unilateral secondary osteoarthritis of knee

Primary outcomes

1

Description

knee adduction moment.

Timepoint

Knee adduction moment measurement using medical insole with a lateral wedge and without the use of a medical insole.

Method of measurement

Force plate.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention will be is to use full-length insoles made of medium hardness ethylene vanilla acetate (EVA) with medial longitudinal arch support, Heel Cup, and lateral wedge. These insoles which will be made according to the length of the person's foot and prosthesis material will be laid inside the standard shoe. Participants will then wear the shoes and walk 5 meters on the force plate, this work will be repeated 5 times to reduce the measurement error.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Musculoskeletal Research Center of Isfahan University

of Medical Sciences

Full name of responsible person

Tahmoures Tahmasebi Notarki

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Faculty of Rehabilitation, West Door of Isfahan
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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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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 Notarki

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Orthotics and Prosthetics

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Person responsible for scientific inquiries

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Person responsible for updating data

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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