Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)

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Recruitment status
Recruitment complete

Funding source

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

Expected recruitment end date
2020-09-22, 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

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Isfehan

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
Tahmores Tahmasebi Notarki

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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

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 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