Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of microprocessor prosthetic ankle controlling via synergy movements idea on motor performance and postural adjustments in unilateral transtibial amputees.

Protocol summary

Study aim

Investigating the effect of using a new prosthetic ankle joint with the ability to automatically adjust the angle of the ankle joint based on the position of the trunk on the motor performance of unilateral below-the-knee amputees.

Design

A crossover clinical trial study with a control group of 5 healthy people and an intervention group of 5 people with unilateral below-the-knee amputations who will undergo three types of intervention and the test will be conducted as an ABC course.

Settings and conduct

First phase: design and manufacture of prosthetic ankle joint Electromechanical ankle prosthetic joint that is designed and manufactured as a prototype in this study. It has an electric motor to move the ankle joint against the direction of the trunk. Phase II: clinical evaluation of the constructed joint and examination of WBR movements At this stage, WBR test will be taken from all people. The test is that the person bends forward until his hand reaches his knee, then he stands again. The test will be done with 10 repetitions. In the intervention group, the test will be performed with SACH foot, single axis and new joints.

Participants/Inclusion and exclusion criteria

middle stump lengths trumatic amputees Not using aids such as canes Absence of orthopedic problems in other Limbs Not having balance problems Not having diabetes Not be elderly Spinal flexibility Have at least five years of experience using prosthesis

Intervention groups

Intervention group is five transtibila amputees. Effects of three types of interventions includes SACH foot, Single axis foot and newly designed ankle joint will be evaluated together.

Main outcome variables

Work done in Joules at the hip, knee and ankle joints Hip, knee and ankle power in watts Anterior-posterior displacement of the center of pressure Angular changes in the hip, knee and ankle joints

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230609058434N1**
Registration date: **2023-06-13, 1402/03/23**
Registration timing: **prospective**

Last update: **2023-06-13, 1402/03/23**
Update count: **0**

Registration date

2023-06-13, 1402/03/23

Registrant information

Name

Morteza Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7711 8523

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-15, 1402/03/25

Expected recruitment end date

2023-07-21, 1402/04/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of microprocessor prosthetic ankle controlling via synergy movements idea on motor performance and postural adjustments in unilateral transtibial amputees.

Public title
Effect of prosthetic foot on balance

Purpose
Basic scienece

Inclusion/Exclusion criteria
Inclusion criteria:
Transtibial Amputees
Exclusion criteria:

Age
From **20 years** old to **60 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
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
No 47, shaghayegh building, shahrake beheshti, babayi highway
City
Tehran
Province
Tehran
Postal code
165113348

Approval date
2022-10-24, 1401/08/02

Ethics committee reference number
IR.IUMS.REC.1401.612

Health conditions studied

1

Description of health condition studied
unilateral transtibilal amputation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Work done on the hip, knee and ankle joints

Timepoint
10 repetitions after using the desired intervention

Method of measurement
Vicon Nexus motion capture platform

2

Description
The power of the hip, knee and ankle joints

Timepoint
10 repetitions after using the desired intervention

Method of measurement
Vicon Nexus motion capture platform

3

Description
Anterior-posterior displacement of the center of pressure

Timepoint
10 repetitions after using the desired intervention

Method of measurement
Vicon Nexus motion capture platform

4

Description
Angular changes of the hip, knee and ankle joints

Timepoint
10 repetitions after using the desired intervention

Method of measurement
Vicon Nexus motion capture platform

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The people of this group will receive

three interventions and after receiving each intervention, the test will be done with 10 repetitions. Interventions will include the use of SACH foot, single axis foot and new ankle joint.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Orthotics and Prosthetics center

Full name of responsible person

Behnam hajiaghayi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Morteza Mohammadi

Position

PHD Student

Latest degree

Master

Other areas of specialty/work

Others

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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)
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
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
The output files of Nexus Vicon program in c3d format

When the data will become available and for how long
The access period starts 6 months after the results are published

To whom data/document is available
Academic and industrial researchers

Under which criteria data/document could be used
In order to integrate with data from other studies to obtain more samples

From where data/document is obtainable
Behnam Hajiaghaei hajiaghaei.b@iums.ac.ir Maryam Jalai jalali.m@iums.ac.ir

What processes are involved for a request to access data/document
In order to request data, correspondence will be done with the thesis supervisor. If the supervisor agrees, the data will be sent

Comments