

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Comparison of Gait Biomechanics and Postural Stability in Transfemoral Amputees using Modified Socket with New Casting System and Quadrilateral Socket

Protocol summary

Study aim

The aims of this study are to determine and comparison of gait kinematic, postural stability and socket comfort in transfemoral amputees using quadrilateral socket and Modified socket with new Casting System.

Design

In this study three transfemoral amputees who meet all the inclusion/exclusion criteria will participate.

Settings and conduct

The aims of this study are to evaluate gait kinematics and postural stability in transfemoral amputees with two types of sockets. For each participant a modified Sockets will fabricate by a dynamic casting system. Postural stability and gait kinematic will investigate within the four consecutive weeks and in two conditions: with quadrilateral socket and with modified socket. Data recording will be by motion analysis system and force plate during walking and standing respectively. All assessments will conduct at motion analysis laboratory of the School of Rehabilitation Sciences of Iran Medical Science University.

Participants/Inclusion and exclusion criteria

Unilateral transfemoral amputees; ages between 18 and 50 years who use of quadrilateral Socket for at least two years, without history of diabetes, Cardiovascular disease or Neurological disorders .

Intervention groups

1- Prostheses with quadrilateral socket 2- Prostheses with modified socket

Main outcome variables

Gait kinematics and postural stability

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181021041400N1**

Registration date: **2019-04-18, 1398/01/29**

Registration timing: **prospective**

Last update: **2019-04-18, 1398/01/29**

Update count: **0**

Registration date

2019-04-18, 1398/01/29

Registrant information

Name

Behnam Hajiaghaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 0947

Email address

hajiaghaei.b@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-05-20, 1398/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Gait Biomechanics and Postural Stability in Transfemoral Amputees using Modified Socket with New Casting System and Quadrilateral Socket

Public title

Effects of Sockets on Amputees' gait and Stability.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Unilateral Transfemoral Amputee Ages: 18-50 years Long or Middle length Residual Limb 10 Meter Walking Ability without Assistive Device. Using Quadi-Lateral Socket Using Prosthesis more than 2 Years.

Exclusion criteria:

Diabetes or vascular disease Orthopedics Problem that Impact on Walking. Amputation in another limbs Neurological Disease

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **3**

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 Iran University of Medical Sciences

Street address

Next to the Milad Tower; Hemmat Highway

City

Tehran

Province

Tehran

Postal code

۱۳۹۹۶۱۴۵۳۵

Approval date

2018-10-28, 1397/08/06

Ethics committee reference number

IR.IUMS.REC.1397.448

Health conditions studied

1

Description of health condition studied

transfemoral amputation

ICD-10 code

S78.1

ICD-10 code description

Traumatic amputation at level between hip and knee

Primary outcomes

1

Description

Velocity

Timepoint

Before Intervention and 7, 14 and 21 days after Intervention

Method of measurement

Motion Analysis System

2

Description

Postural Stability

Timepoint

Before Intervention and 7, 14 and 21 days after Intervention

Method of measurement

Force Plate

3

Description

Gait Kinematics (Trunk Lateral Bending, Pelvic Obliquity, Hip Abduction, Socket Abduction, Step Length)

Timepoint

Before Intervention and 7, 14 and 21 days after Intervention

Method of measurement

Motion analysis system

Secondary outcomes

1

Description

Socket Comfort

Timepoint

Before Intervention and 7, 14 and 21 days after Intervention

Method of measurement

Socket Comfort Index

2

Description

self-selected comfortable Speed

Timepoint

Before Intervention and 7, 14 and 21 days after

Intervention
Method of measurement
Two Minute Walking Test

3

Description
Symmetry Index
Timepoint
Before Intervention and 7, 14 and 21 days after Intervention
Method of measurement
Motion Analysis System

Intervention groups

1

Description
Using Modified Socket in Amputated Side
Category
Rehabilitation

2

Description
Using quadrilateral socket in Amputated Side
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Rehabilitation Sciences , Iran University of Medical Sciences
Full name of responsible person
Behnam Hajiaghaei
Street address
Iran University of Medical Sciences, Faculty of Rehabilitation sciences, ShahNazari St, Mother Sq, Mirdamad Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Seyed Kazem Malakuti
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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
Meria Yazdani
Position
Student
Latest degree
Master
Other areas of specialty/work
Orthotics and prosthetics
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Iran University of Medical Sciences, Faculty of Rehabilitation sciences, ShahNazari St, Mother Sq, Mirdamad Blvd
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Person responsible for scientific inquiries

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Associate professor

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Some data related to the main Variables such as Gait
Kinematics, stability and walking quality will be Shared.

When the data will become available and for how long

It will be Available After Published in Journals and
According to the Laws of the Journal.

To whom data/document is available

It Will be Available for Academic Researcher.

Under which criteria data/document could be used

For scientific research and Rehabilitation Targets

From where data/document is obtainable

Contact with Corresponding Author,

What processes are involved for a request to access data/document

Upon Receipt of the Email and Review of the Applicant's
Objectives, Information will be Sent within One Month .

Comments