Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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+98 21 2222 0947

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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
۱۴۴۹۶۱۴۵۳۵
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 Lenght)
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
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Iran University of Medical Sciences, Faculty of Rehabilitatiion scinces, 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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research@iums.ac.ir
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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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