

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Comparison of the effect of modified prosthetic socket casting and fabricating method with total surface bearing socket on the satisfaction, socket fit and interface stress distribution in the unilateral below knee amputees.

Protocol summary

Study aim

Comparison of the effect of modified prosthetic socket casting and fabricating method with total surface bearing socket on the satisfaction, socket fit and interface stress distribution in the unilateral below knee amputees.

Design

Randomized clinical trial, cross-over-design, single blind, on 8 amputees by using closed envelopes.

Settings and conduct

Orthotics and Prosthetics Center, Sockets will made by casting and modeling of amputee's residual limb for all participants. Patients will not be aware of the differences between the sockets and the order in which they are worn.

Participants/Inclusion and exclusion criteria

Patients with unilateral below knee amputation who is equal or more than 18 years old.

Intervention groups

Intervention group: Modified prosthetic socket and total surface bearing socket. Each patient should wear each socket for one month. The order of wearing sockets is randomly, and assessments will do at the end of each month for each socket.

Main outcome variables

Socket/limb interface pressure, socket fit, satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211019052810N1**

Registration date: **2021-11-07, 1400/08/16**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-07, 1400/08/16**

Update count: **0**

Registration date

2021-11-07, 1400/08/16

Registrant information

Name

Batoul Bagheripour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7771 8906

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2022-03-06, 1400/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of modified prosthetic socket casting and fabricating method with total surface bearing socket on the satisfaction, socket fit and interface stress distribution in the unilateral below knee amputees.

Public title

Below knee prosthesis socket

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Unilateral below the knee amputation minimum residual limb length should be 13 cm from the distal end of the patella to the end of the stump Ability to use both PTB and TSB sockets and gel liner minimum history of 1 year prosthesis usage ability to walk with or without an aid

Exclusion criteria:

Upper limb amputation or dysfunction Very long residual limb for using the shuttle lock Any progressive and non-progressive disability with psychological, neurological, rheumatological and orthopedic mobility problem except unilateral below knee amputation. Patients who are not able to complete the questionnaires due to cognitive problems Volume fluctuations caused by kidney disorders History of skin allergy to gel liner

Age

From 18 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 8

Randomization (investigator's opinion)

Randomized

Randomization description

The order of fitting and molding of each socket is determined randomly by using 2 envelopes in the packets that the patients select them in order.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will not be aware of the order of fit and the differences between the sockets

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of university of Social Welfare and Rehabilitation Sciences

Street address

Daneshjoo.koodakyar

City

Tehran

Province

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Postal code

1985713871

Approval date

2021-06-09, 1400/03/19

Ethics committee reference number

IR.USWR.REC.1400.075

Health conditions studied

1

Description of health condition studied

Unilateral below knee amputation (Right leg)

ICD-10 code

S88.111A

ICD-10 code description

Complete traumatic amputation at level between knee and ankle, right lower leg, initial encounter

2

Description of health condition studied

Unilateral below knee amputation (Left leg)

ICD-10 code

S88.112A

ICD-10 code description

Complete traumatic amputation at level between knee and ankle, left lower leg, initial encounter

Primary outcomes

1

Description

interface pressure

Timepoint

1 month after socket fit

Method of measurement

Force Sensitive Resistors

2

Description

satisfaction

Timepoint

1 month after socket fit

Method of measurement

Persian version of comprehensive lower-limb amputee socket survey questionnaire

3

Description

socket fit

Timepoint

1 month after socket fit

Method of measurement

Standard meter elastic bar and Kinovea software

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Modified prosthetic socket. Due to the study is cross-over-design. All patients admitted to the study should wear each of the sockets in intervention groups 2 and 1 for one month. The order of wearing sockets is random. All the sockets will made by using Polypropylene by an expert Prosthetist.

Category

Rehabilitation

2

Description

Intervention group 2: Total surface bearing socket. Due to the study is cross-over-design. All patients admitted to the study should wear each of the sockets in intervention groups 2 and 1 for one month. The order of wearing sockets is random. All the sockets will made by using Polypropylene by an expert Prosthetist.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Pezham Prosthetics and Orthotics center

Full name of responsible person

Batoul Bagheripour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Hamidreza Khoramkhorshid

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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

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Mohammadali Mardani

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Orthotics and Prosthetics

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Person responsible for scientific inquiries

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Full name of responsible person

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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

Scientific article

When the data will become available and for how long

from 2022

To whom data/document is available

Academic researcher

Under which criteria data/document could be used

Meta-analysis review

From where data/document is obtainable

Bagheripourb.to@gmail.com

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

1 week

Comments**Person responsible for updating data****Contact****Name of organization / entity**

University of social welfare and rehabilitation sciences

Full name of responsible person

Batoul Bagheripour

Position

PhD candidate

Latest degree

Master

Other areas of specialty/work

Others

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