

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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 be 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 be done 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

##### Email address

bagheripourb.to@gmail.com

#### 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

Tehran

## 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 be 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 be 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

#### Street address

No. 1, Alidousti Ave

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Tehran

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1653893811

#### Phone

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#### Email

bagheripourb.to@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

University of social welfare and rehabilitation sciences

#### Full name of responsible person

Hamidreza Khoramkhorshid

#### Street address

Kodakyar, Daneshjoo Blvd

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#### Postal code

1985713871

#### Phone

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#### Email

hrkhkh@yahoo.com

### 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

#### Street address

Koodakyar, Daneshjoo Blvd

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#### Province

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## Person responsible for scientific 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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**Fax****Email**

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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

**Street address**

Evin-Darakeh

**City**

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**Province**