Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
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 stamp Ability to use both PTB and TSB sockets and gel liner minimum history of 1 year prosthetesis 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 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
Street address
No. 1, Alidousti Ave
City
Tehran
Province
Tehran
Postal code
1653893811
Phone
+98 21 7771 8906
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
City
Tehran
Province
Tehran
Postal code
1985713871
Phone
+98 21 7173 2832
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
City
Tehran
Province
Tehran
Postal code
1545913487
Phone
+98 21 2222 7124
Email
natelnoory@yahoo.com

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
Street address
Koodakyar, Daneshjoo Blvd
City
Tehran
Province
Tehran
Postal code
1545913487
Phone
+98 21 2222 7124
Email
natelnoory@yahoo.com

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
Tehran
Province
Tehran
Postal code
1545913487
Phone
+98 21 7771 8906
Fax
Email
bagheripourb.to@gmail.com

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