Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Feasibility of a six-week trial using a localized version of a variable-volume socket in a below-knee amputee regarding satisfaction, function, piston movements of the socket, and residual limb volume

Protocol summary

Study aim
Feasibility of a six-week trial using a localized version of a variable-volume socket in a below-knee amputee regarding satisfaction, function, piston movements of the socket, and residual limb volume

Design
Single Subject

Settings and conduct
This trial will be conducted at the Orthotics and prosthetic rehabilitation center, red cercent population, Hamadan, Iran. Blinding will not be possible.

Participants/Inclusion and exclusion criteria
unilateral transtibial amputation, residual limb length of >15cm, activity level of K2 or greater, at least 6 months of using prosthesis, use of total contact sockets, an age of 18-85 years, normal ROM of lower limb's joints, lack of residual limb sensation neuropathy, lack of background disease or cancer/ knee ligaments injury or laxity & lower limb pain

Intervention groups
A digital of the residual limb will be obtained using anoptical 3D scanning system. Based on the three dimensional shape, an anterior socket shell with a thickness of 7mm will be designed for the patient using solidworks software. The shell will be manufactured with a 3D printer using polylactic acid (PLA) filaments. Polyethylene foam a gel liner will be used as an interface material between the residual limb and the socket. A system consisting of three pads made of PLA will be placed on the posterior side, where the central pad remains fixed, while the lateral pads can move relative to the central section during fitting, enabling controlled compression of the socket. A pulley and disk lock system will be used to increase or decrease the distance between the pads. For final stabilization of the pad positions, a fixing mechanism and straps commonly used in skate shoes will be utilized. To connect the pylon tube, a component will be used that allows for sliding and angular adjustment of the pylon.

Main outcome variables
satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230528058315N5**
Registration date: **2026-04-28, 1405/02/08**
Registration timing: **prospective**

Last update: **2026-04-28, 1405/02/08**
Update count: **0**

Registration date
2026-04-28, 1405/02/08

Registrant information

Name
Nahid Tafti
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 81 3838 1633
Email address
n.tafti@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-22, 1405/03/01

Expected recruitment end date
2026-09-23, 1405/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Feasibility of a six-week trial using a localized version of a variable-volume socket in a below-knee amputee regarding satisfaction, function, piston movements of the socket, and residual limb volume

Public title

Feasibility of using a localized version of a variable-volume socket in a below-knee amputee

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

unilateral transtibial amputation a residual limb length of at least 15 CM An activity level of K2 or Higher At least 8 months using the definitive socket use of total contact socket A BMI less than 28 Normal range of motion in joints of lower limbs lack of sensation neuropathy in the skin of residual limb according to evaluation by semmes wein stain monofilament of 5.7

Exclusion criteria:

diseased to background diseases or a canser a history of knee ligament injury or laxity pain in lower limbs

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **1**

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 Hamadan University of Medical Sciences

Street address

Shahid Fahmideh

City

Hamadan

Province

Hamadan

Postal code

6517838840

Approval date

2026-04-18, 1405/01/29

Ethics committee reference number

IR.UMSHA.REC.1405.018

Health conditions studied

1

Description of health condition studied

transtibial amputation

ICD-10 code

Z89.519

ICD-10 code description

Acquired absence of unspecified leg below knee

Primary outcomes

1

Description

Socket comfort score

Timepoint

After 7 days of use at the baseline of the study and after 49 days of using the new socket.

Method of measurement

Single-Question Socket Comfort Score Questionnaire

2

Description

Total score of the Prosthesis Evaluation Questionnaire (PEQ)

Timepoint

After 7 days of use at the baseline of the study and after 49 days of using the new socket.

Method of measurement

The Persian version of the Prosthesis Evaluation Questionnaire

Secondary outcomes

1

Description

The amount of vertical displacement of the socket relative to anatomical landmarks under different standing conditions

Timepoint

Immediately after receiving the socket, after 7 days of using the socket, and after 49 days of using the socket

Method of measurement

Digital photography

2

Description
Duration of Timed Up & Go test
Timepoint
Immediately after receiving the socket, after 7 days of using the socket, and after 49 days of using the socket
Method of measurement
Instructions for the Timed Up and Go (TUG) test: Upon hearing the signal "Go," the patient rises from a stable chair, walks a distance of three meters, turns around, returns to the chair, and sits down again.

3

Description
residual limb volume from knee joint level to the end
Timepoint
Immediately after receiving the socket, after 7 days of using the socket, and after 49 days of using the socket.
Method of measurement
After determining the knee joint level, an optical scan of the remaining limb will be performed using a Shining 3D Pro HD scanner, and the volume of the remaining limb will be calculated using Geomagic Design X software.

Intervention groups

1

Description
Intervention group: Participant will be assessed at three time points during the use of the volume-adjustable socket: baseline, after 7 days, and after 49 days. Satisfaction will be evaluated using the Socket Comfort Score (SCS) and a prosthetic evaluation questionnaire. The vertical displacement of the socket relative to anatomical landmarks will be assessed through photography. Ambulatory capacity will be measured using the Timed Up and Go (TUG) test, and residual limb volume will be quantified via optical scanning. All evaluations will be conducted at the Mobasher Rehabilitation Center in Hamadan. This study does not include a control group.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
The Orthopedic Technical Center of the Red Crescent Society of Hamadan Province
Full name of responsible person
Mohammad Vahid Fathi
Street address
South Tohid Blvd
City
Hamadan
Province
Hamadan
Postal code
6517838840
Phone
+98 81 3429 5758
Email
Fathi.vahid79@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Alireza Soltanian
Street address
Shahid Fahmideh
City
Hamadan
Province
Hamadan
Postal code
6517838678
Phone
+98 81 3131 4058
Email
Info.research@umsha.ac.ir
Grant name
Vice President for Research and Technology, Hamadan University of Medical Sciences
Grant code / Reference number
49071
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
Nahid Tafti
Position
assistant professor
Latest degree
Ph.D.

Other areas of specialty/work
Rehabilitation management
Street address
Shahid Fahmideh
City
Hamadan
Province
Hamadan
Postal code
6517838840
Phone
+98 81 3838 1571
Email
Na.Tafti@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Nahid Tafti
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Rehabilitation management
Street address
Shahid Fahmideh
City
Hamadan
Province
Hamadan
Postal code
6517838840
Phone
+98 81 3838 1571
Email
Na.Tafti@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Nahid Tafti
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Rehabilitation management
Street address
Shahid Fahmideh
City
Hamadan
Province
Hamadan
Postal code
6517838840
Phone
+98 81 3838 1571
Email
Na.Tafti@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available