Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

comparison of gate adaptability and symmetry outcomes between immediate post-operative prosthesis and classic methods in lower limb amputees

Protocol summary

Study aim

comparison of gait adaptability and symmetry outcomes between the immediate post-operative prosthesis and classic methods in lower limb amputees

Design

a simple randomized clinical trial, two parallel groups, blinded, with 98 participants. Randomized number tables is used for randomization.

Settings and conduct

The initial evaluation for entering the study is done by a surgeon. The intervention group will receive an immediate prosthesis after surgery and perform scheduled exercises for one month, then will receive a final prosthesis. While the control group will receive only the final prosthesis. Tests are performed in the musculoskeletal laboratory with the blind examiner who does not know the group of participants. Also, during data analysis and statistical analysis, the researcher does not know the group of participants.

Participants/Inclusion and exclusion criteria

entrance factors: trans-tibial amputation. informed consent. age between 18 and 80. no entrance to the research: k2 activity level and below. lower limb bilateral amputation. cognition disorder. upper limb amputation. NLP. skin graft. muscle contracture.

Intervention groups

intervention group: Participants in this group receive immediate postoperative prosthesis (ipop) control group: Participants in this group receive classic methods (soft bandage)

Main outcome variables

gait adaptability: difference between heel strike and appeared laser line on the ground gait symmetry: difference of stride length, time, and speed between two legs.

General information

Reason for update

Acronym

IPOP

IRCT registration information

IRCT registration number: **IRCT20220427054675N1**
Registration date: **2023-01-19, 1401/10/29**
Registration timing: **prospective**

Last update: **2023-01-19, 1401/10/29**
Update count: **0**

Registration date

2023-01-19, 1401/10/29

Registrant information

Name

Zahra Taghizadeh Herat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2267 1440

Email address

zahrataghizadehherat@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2024-09-22, 1403/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
comparison of gate adaptability and symmetry outcomes between immediate post-operative prosthesis and classic methods in lower limb amputees

Public title
comparison of gate adaptability and symmetry outcomes between immediate post-operative prosthesis and classic methods in lower limb amputees

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
trans-tibial(below knee) amputee informed consents of patient for entering the research age between 18 to 80

Exclusion criteria:
k2 activity level and below lower limb bilateral amputation cognition disorder upper limb amputation No Light Perception (NLP) skin graft muscle contracture any other musculoskeletal disease that makes the walking by prothesis impossible soft tissue low quality that we concern about the wound remission

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Randomized

Randomization description
this research is a simple randomized controlled trial that random number tables are used before starting the research. even numbers are used for group A (interventional group) and odd numbers are used for group B (control group). To avoid disparity between group sizes, we used replacement randomization. If the disparity exceeded the preset criterion of the study sample size, we generated another randomization list using simple randomization until we achieved a balanced group size.

Blinding (investigator's opinion)
Single blinded

Blinding description
in this study patient could not blinded. doctors and all health providers could not be blinded neither because they are present at the surgery and post-surgery cares. but on the other hand all researchers and laboratory technicians and data analyzers all fully blinded. during musculoskeletal assessments all of the patients are wearing permanent prosthesis which give no information about the post-operative rehabilitation methods. In data extraction period all the subjects names are coded and no information about medical history of patients are provided for analyzers. To prevent revealing verbal communication between the evaluator and the patient, an observer (who does not have any information) will be present at the evaluation site.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
shahidbeheshti university of medical science

Street address
velenjak daneshjoo street medicine school

City
tehran

Province
Tehran

Postal code
1985717443

Approval date
2022-09-11, 1401/06/20

Ethics committee reference number
IR.SBMU.RETECH.REC.1401.415

Health conditions studied

1

Description of health condition studied
trans-tibial (below knee) amputation

ICD-10 code
Z89.5

ICD-10 code description
Acquired absence of leg below knee

Primary outcomes

1

Description
gait symmetry

Timepoint
1, 6, and 12 months after permanent prosthesis application

Method of measurement
measuring of differences between lower limbs stride length, time, and speed.

2

Description
gait adaptability
Timepoint
1, 6, and 12 months after permanent prosthesis application
Method of measurement
1. gait adaptability measurement is done in such a way that a laser line is displayed on the ground one step before the patient arrives and the person must be able to cross it. 2. The ability to cross the obstacle in such a way that one step before the patient arrives A plastic barrier with a height of 15 cm appears and the person must be able to pass through it.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group patients receive immediate post-operative prosthesis as a recovery and rehabilitation method. The immediate prosthesis has a thermoplastic socket, which is padded with 4 mm polyfoam. The volume of the socket can be adjusted through four straps. The patient uses this prosthesis for one month after surgery. In the first 3 days, stretching exercises are done to strengthen the muscles. In the next 3 to 5 days, standing exercises are performed with the application of limited weight (10 pounds on the first day and its gradual increase in the following days to a maximum of half the body weight) (a scale is placed under the patient's foot to accurately apply the amount of pressure). After this course, walking exercises will be done with a walker.
Category
Rehabilitation

2

Description
Control group: In this group patients receive classic methods (soft bandage). For these participants, the stitched area is covered with a soft bandage, and only exercises to strengthen the muscles of the arms and legs are provided to the person in a lying and sitting position.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
emam hossein hospital
Full name of responsible person
Behzad Azimi
Street address
shahid Madani
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 912 358 2761
Email
dr.b.azimi@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Behzad azimi
Street address
koodakyar st. velenjak
City
Tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 23871
Email
info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zahra Taghziadeh Herat
Position
student

Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
no1 ansari alley qeitarieh street
City
Tehran
Province
Tehran
Postal code
1938953130
Phone
+98 21 2267 1440
Email
zahrataghizadehherat@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
seyed mahmoud mousavi ziarati
Position
prosthetist
Latest degree
Master
Other areas of specialty/work
orthotics and prosthetics
Street address
south JanatAbad st.
City
Tehran
Province
Tehran
Postal code
1474667168
Phone
+98 21 4444 8552
Email
mousavi2m@outlook.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zahra Taghizadeh Herat
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
no1 ansari alley qeitarieh street
City
Tehran
Province
Tehran
Postal code
1938953130
Phone
+98 21 2267 1440
Fax
Email
zahrataghizadehherat@sbmu.ac.ir

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
gait parameters Data
When the data will become available and for how long
1402-1403
To whom data/document is available
academic faculty
Under which criteria data/document could be used
retrospective studies
From where data/document is obtainable
writers- email
What processes are involved for a request to access data/document
sending an email including research project documents
Comments