Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Dynamic stability of unilateral above knee amputees using asymmetric prosthesis

Protocol summary

Study aim
The purpose of this study is to evaluate the effect of varying prosthetic mass and prosthetic knee location on dynamic stability in unilateral above knee amputees during walking.

Design
In this study,fifteen unilateral above knee amputees that met all of the inclusion criteria will participate.

Settings and conduct
This study will be conducted at school of rehabilitation sciences. Dynamic stability of the subjects will evaluate in 4 different conditions. 1-no additional mass, 2- Moving knee mass down by 18.35 % of the total shank length, 68% decrease in the shank mass, 7.3% increase in the thigh mass, 3- Moving knee mass down by 36.7 % of the total shank length, 68% decrease in the shank mass, 7.3% increase in the thigh mass, 4-17% increase in the thigh mass, 38% decrease in the shank mass. All participants will carry out four conditions in different sequences and will provided 3-5 min rest break between the tests.. For each of the four conditions, the subjects will be asked to walk at a comfortable speed along a 77.7 m walkway.

Participants/Inclusion and exclusion criteria
Unilateral above knee amputees aged 20 to 60 years old, without history of neurological disorders and cardiovascular abnormalities will participate in the study.

Intervention groups
1-No additional mass, 2- Moving knee mass down by 18.35 % of the total shank length, 68% decrease in the shank mass, 7.3% increase in the thigh mass, 3- Moving knee mass down by 36.7 % of the total shank length, 68% decrease in the shank mass, 7.3% increase in the thigh mass, 4-17% increase in the thigh mass, 63% decrease in the shank mass.

Main outcome variables
Dynamic stability

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160606028310N4**
Registration date: **2018-01-21, 1396/11/01**
Registration timing: **retrospective**

Last update: **2018-01-21, 1396/11/01**
Update count: **0**

Registration date
2018-01-21, 1396/11/01

Registrant information

Name
Mohammad Ali Sanjari
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 2222 8051 ext. 198
Email address
sanjarima@alum.sharif.edu

Recruitment status
Recruitment complete

Funding source
Vice Chancellor for Research and Technology

Expected recruitment start date
2017-02-19, 1395/12/01

Expected recruitment end date
2018-01-21, 1396/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Dynamic stability of unilateral above knee amputees using asymmetric prosthesis

Public title
Effect of asymmetric prosthetesis on the dynamic stability of amputees

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Subjects with unilateral above knee amputation Independent community ambulation with prosthesis without assistance device Age between 20 to 60 years Using prosthesis at least 3 months

Exclusion criteria:
Using medications that may limit the subject's ability to walk. Diabetes or Cardiopulmonary disorders. Neurological disorders. History of lower extremities surgery or orthopedic disorders other than amputation.

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics Committee of Iran University of Medical Sciences

Street address
Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2016-09-22, 1395/07/01

Ethics committee reference number
IR.IUMS.REC 1395.9211503204

Health conditions studied

1

Description of health condition studied
Unilateral above knee amputation

ICD-10 code
S78.1

ICD-10 code description
Traumatic amputation at level between hip and knee

Primary outcomes

1

Description
Dynamic stability

Timepoint
Immediate afte intervention

Method of measurement
Accelerometer (GaitUp)

Secondary outcomes

1

Description
Symmetry indices of walking (SI)

Timepoint
Immediately after intervention

Method of measurement
Accelerometer (GaitUp)

2

Description
prefered walking speed

Timepoint
Immediately after intervention

Method of measurement
2- minute walking test (2MWT)

3

Description
Subject preference

Timepoint
Immediately after intervention

Method of measurement
The subject will be asked to rank the modified prostheses of the four conditions in order of their preferences.

Intervention groups

1

Description
Moving knee mass down by 36.7 % of the total shank length, 68% decrease in the prosthetic shank mass, 7.3% increase in the prosthetic thigh mass
Category
Rehabilitation

2

Description
Moving knee mass down by 18.35 % of the total shank length, 68% decrease in the prosthetic shank mass, 7.3% increase in the prosthetic thigh mass
Category
Rehabilitation

3

Description
17% increase in the prosthetic thigh mass, 38% decrease in the prosthetic shank mass
Category
Rehabilitation

4

Description
Without modification
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Rehabilitation Sciences, Iran University of Medical Sciences
Full name of responsible person
Vahide Moradi
Street address
No. 17, Shahnazari St, Madar Sq, Mirdamad Blvd, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran
City
Tehran
Province
Tehran
Postal code
13487-15459
Phone
+98 21 2222 8051
Email
vahideh.moradi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology
Full name of responsible person
Dr. Morteza Naserbakht
Street address
Hemmat Highway, Iran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
13487-15459
Phone
+98 21 8670 2503
Email
research.m@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research and Technology
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
School of Rehabilitation Sciences, Iran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sanjari
Position
Associate professor/ PhD in Biomechanics
Latest degree
Ph.D.
Other areas of specialty/work
Biomechanics
Street address
No. 17, Shahnazari St., Madar Sq., Mirdamad Blvd., School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran
City
Tehran
Province
Tehran
Postal code
۱۳۴۸۷ - ۱۵۴۵۹
Phone
+98 21 2222 8051
Fax

Email
sanjarima@alum.sharif.edu
Web page address
http://www.sanjari.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
School of Rehabilitation Sciences, Iran University of Medical Sciences
Full name of responsible person
Dr. Mohammad Ali Sanjari
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Biomechanics
Street address
No. 17, Shahnazari St., Madar Sq., Mirdamad Blvd., School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran
City
Tehran
Province
Tehran
Postal code
13487-15459
Phone
+98 21 2222 8051
Fax
Email
sanjarima@alum.sharif.edu
Web page address
http://www.sanjari.ir

Person responsible for updating data

Contact
Name of organization / entity
School of Rehabilitation Sciences, Iran University of Medical Sciences
Full name of responsible person
Vahide Moradi
Position
MSc. in Orthotics and Prosthetics
Latest degree
Master
Other areas of specialty/work
orthotics and prosthetics
Street address
No. 17, Shahnazari St., Madar Sq., Mirdamad Blvd., School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran
City
Tehran
Province
Tehran
Postal code
13487-15459
Phone
+98 21 2222 8051
Fax
Email
vahideh.moradi@gmail.com
Web page address

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
probability of difficulties in sharing data
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