

# 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 prosthesis 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 after 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

preferred 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