

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The immediate effect of anti-pronation foot orthoses on kinematic and kinetics of gait in ACL reconstructed individuals with and without pronated feet

Protocol summary

Study aim

Comparisons of gait biomechanics in ACL reconstructed subjects with and without foot pronation

Design

Thirty male subjects will be volunteered to participate in this study. They will be divided in three groups (1- healthy controls; 2- ACL reconstructed subjects with normal feet; 3- ACL reconstructed subjects with foot pronation).

Settings and conduct

Gait analysis will be done by motion capture systems in biomechanics laboratory in Islamic Azad University, Hamedan, Iran.

Participants/Inclusion and exclusion criteria

The subjects must have ACL reconstructed ligament

Intervention groups

1- Healthy subjects 2- ACL reconstructed subjects with normal feet 3- ACL reconstructed subjects with foot pronation

Main outcome variables

1- Kinematic variables 2- Kinetic variables

General information

Reason for update

Acronym

Gait

IRCT registration information

IRCT registration number: **IRCT20180522039781N1**

Registration date: **2018-06-03, 1397/03/13**

Registration timing: **prospective**

Last update: **2018-06-03, 1397/03/13**

Update count: **0**

Registration date

2018-06-03, 1397/03/13

Registrant information

Name

Morteza Madadi-Shad

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 81 3831 6081

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The immediate effect of anti-pronation foot orthoses on kinematic and kinetics of gait in ACL reconstructed individuals with and without pronated feet

Public title

The gait analysis of ACL reconstructed individuals

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ACL injury of the subjects

Exclusion criteria:

Symptoms of pain, fatigue, and physical limitations in the

subjects Signs of joints diseases,diseases of bones and neuromuscular dysfunction in the subjects

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

Street address

Ahmadi-roshan Ave., Hamedan., Iran

City

Hamedan

Province

Hamadan

Postal code

6515846549

Approval date

2018-05-22, 1397/03/01

Ethics committee reference number

IR.UMSHA.REC1397.118

Health conditions studied

1

Description of health condition studied

The subjects one year post ACL reconstruction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The kinematics and kinetics of lower limb joints during walking

Timepoint

cross-sectional study

Method of measurement

1- Motion control device (3 dimensional camera), 2- Force platform

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: before and after using an anti-pronation foot orthoses (medial arch support insole), the biomechanical analysis of walking in ACL reconstructed individuals with pronated feet (flat feet) will be done by using three-dimensional camera in laboratory.

Category

Treatment - Other

2

Description

Intervention group: before and after using an anti-pronation foot orthoses (medial arch support insole), the biomechanical analysis of walking in ACL reconstructed individuals with normal foot type will be done by using three-dimensional camera in laboratory.

Category

Treatment - Other

3

Description

Control group: before and after using an anti-pronation foot orthoses (medial arch support insole), the biomechanical analysis of walking in normal healthy individuals will be done by using three-dimensional camera in laboratory.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital

Full name of responsible person

Morteza Madadi Shad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bu-Ali Sina University
Full name of responsible person
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Street address
Shahid Ahmadi-roshan Ave., Hamedan., Iran
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buali@basu.ac.ir
Web page address
<https://www.basu.ac.ir/>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Bu-Ali Sina University

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
Bu Ali Sina University
Full name of responsible person
Nader Farahpour
Position

professor
Latest degree
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Other areas of specialty/work
Biomechanics
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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 more 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