

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the influence of new and worn sport shoes on muscular co-contraction and plantar pressure variables during running in individuals with genu varus

Protocol summary

2019-01-25, 1397/11/05

Study aim

Evaluation the influence of sport shoe ageing on muscular co-contraction and plantar pressure variables in individuals with genu varus during running

Design

Triple blind clinical trial with experimental, control and parallel group.

Settings and conduct

This study will be done at Mohaghegh Ardabili University. Present study is a triple blind one. Participants, main researcher and outcome assessor will not aware of the grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals with genu varus; age range between 18 to 35 years old. Non-inclusion criteria: history of lower limb and trunk injuries; history of surgery.

Intervention groups

Intervention group: Genu varus group (running with both new and worn sport shoes in subjects with genu varus). Control group: Healthy group (running with both new and worn sport shoes in healthy subjects).

Main outcome variables

Muscle co-contraction, Ground reaction forces

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170806035517N3**

Registration date: **2019-01-25, 1397/11/05**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-25, 1397/11/05**

Update count: **0**

Registration date

Registrant information

Name

AmirAli Jafarnezhadgero

Name of organization / entity

University of Mohaghegh Ardabili

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 0903

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-21, 1397/09/30

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the influence of new and worn sport shoes on muscular co-contraction and plantar pressure variables during running in individuals with genu varus

Public title

Effect of shoe aging on biomechanical variables

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals with genu varus Age range between 18-35 years old
Exclusion criteria:
History of lower limb and trunk injuries History of surgery

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, main researcher, and output evaluator will kept blind in this study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical comitee of Ardabil University of Medical Sciences

Street address

Daneshgah street

City

Ardabil

Province

Ardabil

Postal code

5619911367

Approval date

2018-11-19, 1397/08/28

Ethics committee reference number

IR.ARUMS.REC.1397.135

Health conditions studied

1

Description of health condition studied

Genu varus

ICD-10 code

M21.1

ICD-10 code description

Varus deformity, not elsewhere classified

Primary outcomes

1

Description

Muscles co-contraction

Timepoint

Before and after 6 months

Method of measurement

Electromyography and force plate systems

Secondary outcomes

1

Description

Ground reaction forces

Timepoint

Before and after 6 months

Method of measurement

Forceplate system

Intervention groups

1

Description

Intervention group: Intervention group include subjects with genu varus who will be tested by wearing new and worn sport shoes. The brand of shoes will be Adidas-climaCool. During intervention period (6 months), the subjects will wear this shoe as maximum as possible during their daily activities.

Category

Diagnosis

2

Description

Control group: Control group includes healthy subjects who will be tested by wearing new and worn sport shoes. The brand of shoes will be Adidas- climaCool. During intervention period (6 months), the subjects will wear this shoe as maximum as possible during their daily activities.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Mohaghegh Ardabili University

Full name of responsible person

AmirAli Jafarnezhadgero

Street address

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Province

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Phone

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Email

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Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Ergonomics

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

AmirAli Jafarnezhadgero

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ardabil 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**

Ardabil University of Medical Sciences

Full name of responsible person

AmirAli Jafarnezhadgero

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

AmirAli Jafarnezhadgero

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Ardabil University of Medical Sciences

Full name of responsible person

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Raw data and SPSS file

When the data will become available and for how long

After the end of the study

To whom data/document is available

All people

Under which criteria data/document could be used

After publication of manuscripts

From where data/document is obtainable

AmirAli Jafarnezhadgero

What processes are involved for a request to access data/document

Requesting by E-mail

Comments