

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

kinetics, kinematics, and electromyography parameters of gait with the applied reaction forces on the foot in the diabetic patient and control group

Protocol summary

Summary

One of the most common metabolic disorders is diabetes. Various factors such as life style, nutrition are effect on rapid prevalence. Currently, more than 7 million people have diabetes in Iran. Until 2035, world diabetes prevalence expects to reach 592 million. Diabetes associated with functional alteration (neuropathy, decreased range of motion joints, vasculopathy) and structural alteration (foot deformities, skin changes, and muscle atrophy) in the foot. Gait strategy in diabetes patient is conservative. This means that the speed of gait was reduced, width of the base of support was increased, and support phase time and stride time were prolonged. Horizontal and vertical reaction forces of the diabetic patients were less and more than that healthy subject respectively. Aim of this study is the evaluation of reaction force, moment, and muscle activity on the lower limb during in females' diabetic and healthy subjects. After careful examination, we will choose 45 females with same demographic characteristic. We are going to use four VICON cameras (200 Hz), two Kistler force plates (1000 Hz), and BTS Free EMG 300 at same time. We will use special software for extracting date. Finally, results will have analyzed with SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112331058N1**

Registration date: **2017-03-13, 1395/12/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-13, 1395/12/23

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

institution

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

kinetics, kinematics, and electromyography parameters of gait with the applied reaction forces on the foot in the diabetic patient and control group

Public title

Effect of diabetes on biomechanal factors of gait

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: Diabetes type II, lack of acute problems in heart, vision, Kidney Exclusion criteria: Fracture

history, diabetic ulcer

Age
From **25 years** old to **70 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamedan university of medical science

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Khaje Rashid st. Ayatollah Kashany Av. Hamedan
university of medical science

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Postal code

Approval date

2017-01-14, 1395/10/25

Ethics committee reference number

IR.UMSHA.REC.1395.469

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E10-E14

ICD-10 code description

Diabetes mellitus

Primary outcomes

1

Description

kinematic, Kinetic and electromyography

Timepoint
after 6 months of ending screening

Method of measurement
VICON system, force plate and Surface EMG

2

Description

Neuropathy

Timepoint

pre-intervention

Method of measurement

questionnaire

Secondary outcomes

1

Description

Comparison of diabetes' effect on the biomechanic's gait

Timepoint

After 4 months of assembling data with mentioned
devices

Method of measurement

Special software of the each device

Intervention groups

1

Description

Massage Therapy

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Hami Health and diabetes clinic

Full name of responsible person

Dr. Nasrin Khorami

Street address

Jahad st., Nazari Av., Hoveizeh Av.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bu-Ali Sina University

Full name of responsible person

Dr. Nader Farahpour

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Ahmadi Roshan st. Bu-Ali Sina University

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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
Bu-Ali Sina University

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty