

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

16 Jun 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 data. 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

##### Name

Hananeh Younesian

##### Name of organization / entity

Bu-Ali Sina University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 473 1015

##### Email address

h.younesian@basu.ac.ir

#### 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 biomechanical 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  
**Street address**  
Khaje Rashid st. Ayatolah Kashany Av. Hamedan  
university of medical science  
**City**  
Hamedan  
**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.  
**City**  
Hamedan

## Sponsors / Funding sources

### 1

**Sponsor**  
**Name of organization / entity**  
Bu-Ali Sina University  
**Full name of responsible person**  
Dr. Nader Farahpour  
**Street address**  
Ahmadi Roshan st. Bu-Ali Sina University

**City**  
Hamedan

**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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Dr. Nader Farahpour

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## Person responsible for scientific inquiries

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Ph.D student, Biomechanic, Physical Education

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## Person responsible for updating data

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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*