

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The Effect of The Toe Rocker on The Gait Kinematics and Temporal Spacial Parameter in Diabetics Type II Patients, Single Subject Design (SSD)

Protocol summary

Summary

This study will be done on a subject with Diabetes Mellitus type II. The aim of this study is assessment of the effect of toe rocker on gait kinematics and temporal-spatial parameters. To perform this study, the inclusion and exclusion criteria will be matched to the volunteers and after that one subject will be selected to participate in this study. This study is designed to be performed in two phases: the base phase and the intervention phase. The base phase will be done at first and when having no orthotic intervention. The base phase has 5 trials that will be done with equal intervals. The base phase will be performed in 5 weeks, every week one session. When the base phase finished, the appropriate orthoses with the toe rocker will be fabricated for the participant. Then the orthosis will be delivered to the participant and after a week the intervention phase will be started. The intervention phase will be done in 5 trials with equal intervals, like the base phase. For the statistical analysis, visual analysis will be used. The appropriate method to detect significant difference between the base phase and the intervention phase, the celeration line method will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016090429684N1**
Registration date: **2017-05-04, 1396/02/14**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-05-04, 1396/02/14

Registrant information

Name

Kourosh Barati

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences, Student research commitment

Expected recruitment start date

2017-07-01, 1396/04/10

Expected recruitment end date

2017-12-17, 1396/09/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of The Toe Rocker on The Gait Kinematics and Temporal Spacial Parameter in Diabetics Type II Patients, Single Subject Design (SSD)

Public title

The Effect of Toe Rocker on The Gait Kinematics and Temporal Spacial Parameter in Diabetics Type II Patients, Single Subject Design (SSD)

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: diabetics type 2 that have normal gait pattern and muscle strength exclusion criteria: History of musculoskeletal disorders in lower limb History of lower limb trauma Using lower limb orthosis History of lower limb operation Gait abnormalities that are detectable with eyes, for example: lateral bending, backward bending and hyper lordosis, forward bending in gait initiation, leg length discrepancy, hyper extension/ flexion in knee

Age

From **15 years** old to **55 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **1**

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

Ethics Committee of Iran University of Medical Sciences

Street address

Hemmat expansion, Tehran, Iran

City

Tehran

Postal code

Approval date

2016-08-31, 1395/06/10

Ethics committee reference number

IR.IUMS.REC.1395.27721

Health conditions studied

1

Description of health condition studied

Dyabetics type II

ICD-10 code

E11

ICD-10 code description

diabetes (mellitus)(nonobese)(obese): adult-onset maturity-onset nonketotic stable type II non-insulin-dependent diabetes of the young

Primary outcomes

1

Description

The kinematics parameter

Timepoint

5 week in the base phase without using orthosis and 5 weeks in the intervention phase after delivering the intervention

Method of measurement

Motion analysis instrument

2

Description

temporal spacial parameter

Timepoint

5 week in the base phase without using orthosis and 5 weeks in the intervention phase after delivering the intervention

Method of measurement

Motion analysis instrument and force plate

Secondary outcomes

empty

Intervention groups

1

Description

Toe rocker

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

the hospitals that are managed by the Iran University of Medical Sciences

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences, the student research committee

Full name of responsible person

Koorosh Barati

Street address

Hemmat expansion, Tehran, Iran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences, the student research committee

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

Name of organization / entity

IUMS

Full name of responsible person

Koorosh Barati

Position

PhD candidate

Other areas of specialty/work

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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