Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of 6 weeks endurance training of knee muscles on EMG parameters in patients with type 2 diabetes mellitus

Protocol summary

Study aim

- Evaluation of the effect of six weeks of endurance training on the parameters of RMS derived from EMG in patients type 2 diabetes - The effect of six weeks of endurance training on frequency parameters of EMG in type 2 diabetic patients - Comparison of frequency parameters derived from EMG in type 2 diabetic patients with healthy subjects matched before exercise - Comparison of frequency parameters of EMG in type 2 diabetic patients with healthy individuals matched after 18 sessions of endurance training

Design

In this study, a patient group was received interventions and a group of healthy individuals matched with the patient group was compared.

Settings and conduct

The location of the project Was in Karaj

Participants/Inclusion and exclusion criteria

1. Men and women aged 40 to 60 years with non-insulin dependent type 2 diabetes that past 5 to 10 years from the disease. 2. Controlled diabetes. 3. Ability to do sports movements 4. Lack of any central and peripheral neurological disease, orthopedic lesions, retinopathies, foot ulcers, renal, hepatic, respiratory, cardiac and thyroid disorders. 5. Exercise has not been carried out professionally or regularly during the past two years. 6. FBS before testing 150-110. 7. 7% <HbA1c <9% 8. Blood pressure below 90/140 9. Non-drug and alcohol addiction 10. Not having major surgery affecting the lower extremity or history of knee and ankle instability 11. The ability to maintain the state in all three basic balance tests for more than 30 seconds. 12 Neuropathy. 13- 18.5 <BMI <30

Intervention groups

In this plan, endurance training for knee muscles of patients were done that exercise intensity was between 12-15 according to the Borg Scale. There was a healthy group for comparison with diabetics who were matched with the group of patients.

Main outcome variables

Change in frequency and time domain of EMG

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190417043299N1**
Registration date: **2019-06-21, 1398/03/31**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-21, 1398/03/31**
Update count: **0**

Registration date

2019-06-21, 1398/03/31

Registrant information

Name
Seyed Ahmad Bagherian
Name of organization / entity
Tabriz university of medical sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-27, 1398/02/07

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of 6 weeks endurance training of knee muscles on EMG parameters in patients with type 2 diabetes mellitus

Public title

Investigating the effect of endurance training on muscles in type 2 diabetes mellitus patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 diabetic patients with 5 to 10 years disease duration Ability to do sports movements Not to exercise professionally or regularly during the 2 last ears FBS before testing is 110-150 Blood pressure below 140/90 The BMI between 18.5-30

Exclusion criteria:

Neurological diseases, orthopedic lesions, retinopathy, foot ulcer, renal failure, liver failure, respiratory failure, cardiac failure, and thyroid failure Drug and Alcohol Addiction Problem in functional balance Neuropathy

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee of Ethics in Research at Tarbiat Modares university

Street address

Tarbiat Modares University, Jalal-Al-Ahmad St.

City

Tehran

Province

Tehran

Postal code

1411713116

Approval date

2019-01-27, 1397/11/07

Ethics committee reference number

IR.MODARES.REC.1397.248

Health conditions studied

1

Description of health condition studied

Diabetes mellitus type 2

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Changes in the mean frequency, median frequency and RMS of muscles before and after exercises

Timepoint

At the beginning of the study, six weeks after the initial assessment and beginning of the training, 24 hours after the end of the 18 training sessions

Method of measurement

Using the EMG device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The patient received 18 sessions of endurance training in 6 weeks with a weight. First, the patient's heart rate and blood glucose was recorded. The exercise program was warm-up, exercise with 60% 1RM with repetition of 25-30-35 and exercise intensity with the Borg Scale was controlled and the number of the questionnaire was 12-15, and finally the body cool-down.

Category

Treatment - Other

2

Description

Control group: Among healthy non-athlete volunteers, a group was selected which matched the age, BMI and other factors with the diabetic group. The knee muscles of this group were also recorded by EMG, which was used

as a benchmark for comparison with the diabetic group before and after the 18 exercises. The healthy group did not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Mahdi Dehghani specialized clinic

Full name of responsible person
Mahdi Dehghani Mohammad Abadi

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Unit 15, 4th floor, Noor Doctors Building, next to City Book Building, Shahid Beheshti St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tarbiat Modares University

Full name of responsible person
Yaaghoub Fath Allahi

Street address
The University of Tarbiat Modares, Jalal-Al-Ahmad St.

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Res@modares.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Tarbiat Modares 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
Tarbiat Modares University

Full name of responsible person
Seyed Ahmad Bagherian

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All information can be shared after making the subjects unidentifiable.

When the data will become available and for how long
6 months after publication of results

To whom data/document is available
All individuals can use information about the results of the study.

Under which criteria data/document could be used
To treat diabetic patients and to carry out new research in this field, data can be used with unidentifying individuals of the study.

From where data/document is obtainable
They can contact the researcher by email They can meet the Physical Therapy Department of Tarbiat Modares University

What processes are involved for a request to access data/document
The requestor should explain the cause of the need for the data clearly and if the reasons are convincing, the data will be available to him.

Comments