

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of two exercise- therapy programs on indices of muscular strength in female type 2 diabetes mellitus patients: a double blind randomized controlled trial.

Protocol summary

Summary

This study is a double-blind controlled trial to investigate and comparison of the effects of two exercise-therapy protocols on indices of isokinetic muscular strength in a total of 40 female volunteers with type 2 diabetes mellitus aged 30-60 years with and HbA1C=7.5-10% and treated with oral antidiabetic agents and no major cardiovascular risk factor or other contraindications to moderate to high intensity endurance and resistance exercises. The subjects will be randomized to two groups of twenty each. The intervention group will receive 12 weeks of supervised endurance and resistance exercises, while the control group will be receiving a home-based individualized endurance and resistance exercise program for the same duration of time. Both of the abovementioned protocols will be complying with American of Sports Medicine and American Diabetes Association guidelines In both groups concentric and eccentric peak torque, and concentric and eccentric average torque of non-dominant knee extensors at three different angular velocities will be measured and compared before and after the interventions using a Biodex® isokinetic dynamometry system.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104256283N1**
Registration date: **2011-12-27, 1390/10/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-27, 1390/10/06

Registrant information

Name

Mojtaba Malek

Name of organization / entity

Institute of Endocrinology and Metabolism, Endocrine research center(Firozgar), Tehram University of

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 5247

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malekmoj@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Tehran University of Medical Sciences

Expected recruitment start date

2011-05-22, 1390/03/01

Expected recruitment end date

2012-11-22, 1391/09/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two exercise- therapy programs on indices of muscular strength in female type 2 diabetes mellitus patients: a double blind randomized controlled trial.

Public title

Comparison of two exercise- therapy programs on indices of muscular strength in female type 2 diabetes mellitus patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Type 2 diabetes mellitus; Age range: 30-55 years; Female; Treated by Oral Anti Diabetic agents; HbA1C=8-10%. Exclusion criteria: High blood pressure; Insulin therapy; B-Blocker agents; Ca- Channel blockers; Nitrates; Cardio Vascular Diseases; Micro vascular and Macro vascular side effects of Diabetes Mellitus; History of moderate to sever musculoskeletal disorders; Anemia (Hb lower than 12); Pregnancy; Tobacco smoking; Alcohol abuse.

Age

From **30 years** old to **55 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Keshavarz Blv., Poorsina Building, Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

12667

Health conditions studied

1

Description of health condition studied

Exercise therapy programs in Non-insulin-dependent diabetes mellitus type II

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Strenght changes of concentric and eccentric muscles

Timepoint

72-96 hours before the initiation of the protocols , 72-96 hours after the conclusion of the protocols.

Method of measurement

Isokinetic test by Kin Kam device

Secondary outcomes

1

Description

Eccentric average torque of non-dominant knee extensors.

Timepoint

72-96 hours before the initiation of the protocols , 72-96 hours after the conclusion of the protocols.

Method of measurement

Isokinetic test

2

Description

Maximal concentric angular velocity of non-dominant knee extensors.

Timepoint

72-96 hours before the initiation of the protocols , 72-96 hours after the conclusion of the protocols.

Method of measurement

Isokinetic test

3

Description

Eccentric peak torque of non-dominant knee extensors.

Timepoint

72-96 hours before the initiation of the protocols , 72-96 hours after the conclusion of the protocols.

Method of measurement

Isokinetic test

4

Description

Concentric average torque of non-dominant knee extensors

Timepoint

72-96 hours before the initiation of the protocols , 72-96

hours after the conclusion of the protocols.

Method of measurement

Isokinetic test

5

Description

Maximal eccentric angular velocity of non-dominant knee extensors.

Timepoint

72-96 hours before the initiation of the protocols , 72-96 hours after the conclusion of the protocols.

Method of measurement

Isokinetic test

Intervention groups

1

Description

Supervised exercise protocol (SEP)

Category

Other

2

Description

Home-based exercise protocol (HEP)

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Institute of Endocrinology and Metabolism, Endocrine Research center(Firozgar)

Full name of responsible person

Street address

Firozgar alley, Valadi St., Behafarin St., Karimkhan Ave., Vali-asr Sq.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Fotouhi

Street address

Keshavarz Blv., Poorsina Building, Tehran University of Medical Sciences

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Tehran University of Medical Sciences

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

Endocrine research center (Firozgar), Tehran University of Medical Sciences

Full name of responsible person

Dr Laily Najafi

Position

Deputy of Research

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences, Endocrine Research center (Firozgar),

Full name of responsible person

Dr Mojtaba Malek

Position

Vice chancellor for research of Endocrine research center (Firozgar)

Other areas of specialty/work

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

Endocrine research center (Firozgar)

Full name of responsible person

Dr Mojtaba Malek

Position

Vice Chancellor for research of Endocrine research center (Firozgar)

Other areas of specialty/work**Street address**

Firozgar Alley, Valadi St., Behafarin St., Karimkhan Ave., Vali-asr Sq.

City

Tehran

Postal code**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