

# 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

##### Email address

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

##### Street address

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

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##### Postal code

##### Phone

+98 21 8894 5247

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l.najafi@yahoo.com

##### Web page address

## 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

##### Street address

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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*