

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Effects of Moderate-Intensity Exercise with Momordica Charantia L. on serum Glycemic indexes, reverse cholesterol transport elements and Lipocalins (RBP-4 and Lcn-2) in Men with Type 2 Diabetes

Protocol summary

Study aim

The aim of this study was to examine the Protective Effect of aerobic training along with Momordica charantia L on Hyperglycemia control indexes reverse cholesterol transport elements and Lipocalins (RBP-4 and Lcn-2) in man with type 2 diabetes.

Design

36 men with type 2 diabetes selected from Tehran and randomly divided into four groups (Control-Water, Control-Momordica charantia, Control-Training and Momordica charantia+Training). Training group's perform Aerobic Training for for eight weeks, three sessions a week (40% to 70% of the reserved heart rate and for 15 to 45 min). Control-Momordica charantia and Momordica charantia+Training will feed 2000 mg of Momordica charantia for eight weeks (Twice a day before breakfast and dinner).

Settings and conduct

Intervention Research, Tehran City The location of the research is the Iran Football Medical Assessment and Rehabilitation Center (IFMARC), which has already been coordinated. In this research, people who work with subjects are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Type 2 Diabetes; Not having regular physical activity; Without receive insulin Exclusion criteria: Have Heart and Kidney failure; Inability to Training; Have Musculoskeletal Disorders

Intervention groups

Aerobic Training and Momordica charantia L

Main outcome variables

Effect of aerobic training with Momordica charantia L on Hyperglycemia control indexes such as: GLP-1, DPP-4, GLP, Glucose, Insulin, Insulin resistance and APO-a1, APO-E, Lcn-2, RBP4

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161218031451N2**

Registration date: **2019-11-05, 1398/08/14**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-05, 1398/08/14**

Update count: **0**

Registration date

2019-11-05, 1398/08/14

Registrant information

Name

Orod Mohajer Iravani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2330 2233

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-06, 1398/06/15

Expected recruitment end date

2019-11-06, 1398/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Moderate-Intensity Exercise with Momordica Charantia L. on serum Glycemic indexes, reverse cholesterol transport elements and Lipocalins (RBP-4 and Lcn-2) in Men with Type 2 Diabetes

Public title

Effect of training and Momordica charantia L on diabetes

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 Diabetes Not having regular physical activity
Without receive insulin At least 45 years old

Exclusion criteria:

Have Heart and Kidney failure Inability to Training Have
Musculoskeletal Disorders

Age

From **45 years** old to **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **36**
More than 1 sample in each individual
Number of samples in each individual: **9**
Men with Type 2 Diabetes

Randomization (investigator's opinion)

Randomized

Randomization description

In this research, subjects are selected Simple randomization by random allocation rule. After determining the sample size, they will be equally divided into four groups (Control-Water, Control-Momordica charantia, Control-Training and Momordica charantia+Training).

Blinding (investigator's opinion)

Single blinded

Blinding description

The Control-Momordica charantia and Momordica charantia+Training patients receive Momordica charantia (2000 mg/day), two capsules orally of 500 mg twice daily before breakfast and dinner for 8 weeks. Control-Water and Control-Training groups receive placebo in the same pharmacological presentation. Starch is used as placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Sport Sciences Research Institute of Iran

Street address

Motahari Ave., Miramad St., No. 5th Lane

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Province

Tehran

Postal code

1587958711

Approval date

2019-03-11, 1397/12/20

Ethics committee reference number

IR.SSRC.REC.1398.008

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Effect of aerobic training and Momordica charantia L on
GLP-1

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

2

Description

Effect of aerobic training and Momordica charantia L on
GIP

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

3

Description

Effect of aerobic training and Momordica charantia L on
DPP-4

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

4

Description

Effect of aerobic training and Momordica charantia L on Insulin Resistance

Timepoint

Before and after the protocol

Method of measurement

HOMA-IR METOD

5

Description

Effect of aerobic training and Momordica charantia L on APO-a1

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

6

Description

Effect of aerobic training and Momordica charantia L on APO-E

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

7

Description

Effect of aerobic training and Momordica charantia L on LCN-2

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

8

Description

Effect of aerobic training and Momordica charantia L on RBP4

Timepoint

Before and after the protocol

Method of measurement

Biochemical and laboratory methods

Secondary outcomes

empty

Intervention groups

1

Description

Control group: in this group we have not any intervention during 6 weeks, and will consider this group as placebo.

Category

Placebo

2

Description

Intervention group: Training group (in this group for six week, three session/weeks), the training start with 10 min warming and then 25 min training with 60 Vo2max, on go up to every day 2 min increase to the training time up 45 min until the end of intervention with 75 vo2 max).

Category

Treatment - Other

3

Description

Intervention group: Momordica charantia group (in this group eat 2000 mg of Momordica charantia for eight weeks Twice a day before breakfast and dinner).

Category

Treatment - Other

4

Description

Intervention group: Momordica charantia- Training group (In this group the Simultaneous intervention, Momordica charantia and training, will treat with the same protocol that describe at the previous part).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Diabetes Association

Full name of responsible person

Ahmad Abdi

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Ayatollah Amoli Branch, Islamic Azad University

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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**

Islamic Azad University

Full name of responsible person

Ahmad Abdi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Sport Medicine

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The report is submitted to the research department of the university. Also published as a paper.

When the data will become available and for how long

Since 2020

To whom data/document is available

All researchers

Under which criteria data/document could be used

Citing references

From where data/document is obtainable

Scientific bases and Ayatollah Amoli Branch, Islamic Azad University, amol, Iran

What processes are involved for a request to access data/document

Maximum one week

Comments