

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of the effect of 8 weeks of different training (aerobic, resistance and combination) on serum levels of nesfatin-1 and insulin resistance index in women with type 2 diabetes

Protocol summary

Study aim

Comparison of the effect of 8 weeks of different training (aerobic, resistance and combination) on serum levels of nesfatin-1 and insulin resistance index in women with type 2 diabetes

Design

Clinical trials with control group, with parallel groups, randomized

Settings and conduct

Among 100 women with type 2 diabetes in Shahroud, 100 eligible people were enrolled in the study. Finally 60 volunteers were selected to participate in this research at Shahrood University of Technology.

Participants/Inclusion and exclusion criteria

En The inclusion criteria were: having been suffering from T2DM (fasting blood sugar ≥ 126 mg/dl and 2-hour postprandial blood glucose ≥ 200 mg/dl) for at least 2 years; Women 45 to 60 years old / exclusion criteria: diagnosed with any other diseases

Intervention groups

Aerobic training group, resistance training group, combined training group (aerobic resistance) and control group

Main outcome variables

Nesfatin-1

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180806040721N1**

Registration date: **2018-10-03, 1397/07/11**

Registration timing: **retrospective**

Last update: **2018-10-03, 1397/07/11**

Update count: **0**

Registration date

2018-10-03, 1397/07/11

Registrant information

Name

Roghayeh Koroni

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-02, 1396/04/11

Expected recruitment end date

2017-09-06, 1396/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of 8 weeks of different training (aerobic, resistance and combination) on serum levels of nesfatin-1 and insulin resistance index in women with type 2 diabetes

Public title

Comparison of the effect of 8 weeks of different training (aerobic, resistance and combination) on serum levels of nesfatin-1 and insulin resistance index in women with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The inclusion criteria were: having been suffering from T2DM (fasting blood sugar ≥ 126 mg/dl and 2-hour postprandial blood glucose ≥ 200 mg/dl) for at least 2 years; old Women 45 to 60 years

Exclusion criteria:

exclusion criteria: diagnosed with any other diseases

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahroud University of Medical Sciences

Street address

Tehran street

City

Shahroud

Province

Semnan

Postal code

71-545-121

Approval date

2018-07-22, 1397/04/31

Ethics committee reference number

IR.SHMU.REC.1397.080

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Nesfatin-1

Timepoint

At the beginning of the study (before the intervention) and 2 months after the intervention, it was measured.

Method of measurement

The serum level of nesfatin-1 was measured using the Sandwich Elisa method and using the Eastbiopharm human kit / country-China manufacturing.

2

Description

Insulin resistance index

Timepoint

At the beginning of the study (before the intervention) and 2 months after the intervention, it was measured.

Method of measurement

Insulin resistance index using formula = fasting insulin ($\mu\text{U} / \text{ml}$) \times fasting glucose (mmol / L) / 22.5

Secondary outcomes

1

Description

Glucose/ Insulin- Insulin resistance

Timepoint

At the beginning of the study (before the intervention) and 2 months after the intervention, it was measured.

Method of measurement

The glucose level was measured using the Colorimetric Enzymatic method and using the human kit of Iran Pars Tesh T Persian Company. Insulin levels were measured by Insulin ELISA in the United States. Insulin resistance with the formula: fasting glucose (mmol / L) \times fasting insulin ($\mu\text{U} / \text{ml}$) / 22/5

Intervention groups

1

Description

Intervention group: Aerobic training group Participants of this group performed their activities using treadmill or bicycle three times per week (on non consecutive days). Time of exercise was increased from 20 minutes per session (at 60% of maximum heart rate) to 60 minutes (at 75% of maximum heart rate) per session. Heart rate was regularly determined by the monitor's treadmill or cycle ergometers. Required heart rate was calculated by the Karvonen formula

Category

Treatment - Devices

2**Description**

Intervention group: Resistance training group This program was performed on different weight machines. Correct training techniques were instructed and supervised by professional trainers. The protocol was started on 2 days of the week during the first month and was increased to 3 non-consecutive days per week. Training was started during weeks 1 and 2 with intensity 60% onerepetition maximum (1RM) and was progressed to intensity 75-80% 1RM. The number of sets was 1-2 during the first month. This program included 10 different exercises for upper and lower body. Participants performed 3 sets of 8-10 repetitions (with a 90- 120 s rest between sets) of the following exercises: bench press, seated row, shoulder press, chest press, lateral pulldown, abdominal crunches, leg press, leg extension, triceps pushdown and seated bicep curls

Category

Treatment - Devices

3**Description**

Intervention group: Combined training group (aerobic-resistance) The subjects of this group did the aerobic exercise plus resistance training programs 3 times a week. After a warm-up stage, they worked for 20-30 minutes on a treadmill or bicycle plus 2 sets of each of 8 exercises with 8-10 repetitions on weight machines

Category

Treatment - Devices

4**Description**

control group:control group A group that did not have any training intervention.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Hossein Hospital in Shahrood

Full name of responsible person

Dianatinasab Mostafa

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Tehran Street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahroud University of Medical Sciences

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?**

Yes

Title of funding source

Shahroud University of Medical Sciences

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**

Shahroud University of Medical Sciences

Full name of responsible person

Dianatinasab Mostafa

Position

Epidemiologist

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The epidemic is the consent of the participants to disseminate their information and data

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The total potential data can be shared after unidentifiable people

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Only for scholars working in academic institutions

Under which criteria data/document could be used

Only numerical analysis can be used.

From where data/document is obtainable

Mostafa Dianatinasab with Email Address:
dianati.epid@yahoo.com

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

It takes 2 months.

Comments