Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Nov 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

Country
Iran (Islamic Republic of)

Phone
+98 71 5383 4816

Email address
r.koroni@shahroodut.ac.ir

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
Diabets
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 (µU / ml) × fasting glucose (mmol / L) / 22.5

Secondary outcomes

1

Description
Glocose/ 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) * fasting insulin (µU / 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
Street address
Tehran Street
City
Shahrood
Province
Semnan
Postal code
71-535121
Phone
+98 23 3234 2421
Email
dianati.epid@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Mohammad Hossein Emamiyan
Street address
Tehran Street
City
Shahrood
Province
Semnan
Postal code
71-535121
Phone
+98 23 3223 4221
Email
mohhamad.epid@yahoo.com
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
Epidemiology
Street address
Tehran Street
City
Shahrood
Province

Semnan
Postal code
71-535121
Phone
+98 23 3223 4521
Email
dianati.epid@yahoo.com

Person responsible for scientific 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
Epidemiology
Street address
Tehran Street
City
Shahrood
Province
Semnan
Postal code
71-535121
Phone
+98 23 3223 4521
Email
dianati.epid@yahoo.com

Person responsible for updating data

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
Epidemiology
Street address
Tehran Street
City
Shahrood
Province
Semnan
Postal code
71-535121
Phone
+98 23 3223 4521
Email
dianati.epid@yahoo.com

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