Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effecf of 8-weeks combined exercise with omega-3 and l-carnitine supplement consumption on serum level visfatin in women with type 2 diabetes.

Protocol summary

Summary

The overall purpose: Effect of 8 weeks of combined training while taking supplements of omega-3 and L-carnitine on the level of visfatin in type 2 diabetic women Specific objectives 1-determine the effect of 8 weeks of combined training on visfatin in type 2 diabetic women (2) the effect of 8 weeks of combined training with omega-3 supplementation on serum visfatin in type 2 diabetic women 3-determine the effect of 8 weeks of combined training with supplementation of L - carnitine on the level of visfatin in type 2 diabetic women 4. determine the effect of two omega-3 and L-carnitine supplementation on serum visfatin in type 2 diabetic women 5-determine the effect of 8 weeks of training, combined with the simultaneous intake of omega-3 supplements L - carnitine level of visfatin in type 2 diabetic women Methods: This quasi-experimental.The population of this study included women with type 2 diabetes, Diabetes Association, referring to the city will form a voluntary basis and are chosen randomly. The research design includes pre-test and post-test experimental group and a control group is 5./ 160 mm Hg have. Exclusion criteria included insulin injections after the onset of the secondary complications of diabetes, such as protocol and having eye, kidney, diabetic foot ulcers and amputation and heart disease - cardiovascular, and inflammation.randomly in six groups are: group exercise + placebo, exercise omega-3 supplementation, exercise + L - carnitine, exercise + omega 3 + supplement L-carnitine, omega 3 + L-carnitine and the control group (control group there was no activity during the period of investigation (ordinary, everyday practices) and its difference with other groups in supplements and practice, as well as other groups of drugs to lower blood glucose, lipids and blood pressure with the same dose used) . At the beginning and end of 8 weeks of using the device Body Composition (Korea), body composition, including weight, BMI, percent body fat mass and percentage of body fat and lean body mass, etc., is measured. As well as systolic and diastolic blood pressure of the subjects to be measured with a mercury sphygmomanometer. Blood sugar glucose test participants with finger (Korea) will be measured. Blood samples from participants once the first stage (pre-test) morning after 10 hours of fasting at a rate of 10 cc in the sitting position load the second (post-test) 24 hours after the last training session (8 weeks) and consuming supplements taken fasting is. The Omega 3 for 8 weeks and every two capsules containing omega-3 dose of 2000 mg each capsule contains 1000 mg of omega-3 (EPA 360 mg) and DHA240 mg) and Group L - carnitine also provides 500 mg of L - carnitine 2 hours before exercise given that along with 200 ml of water consumption.The training protocol: total exercise duration is about 180 -190 minutes per week of 30 minutes of aerobic exercise and resistance training 3 times a week is V40-30 minutes. Participants in the first session after 10 minutes of warm-up program, with an intensity of 70-60% of maximum heart rate for 20 minutes on the treadmill walk. To determine exercise intensity, maximum heart rate is calculated with the formula -220 age. After 5 minutes of rest, participants will participate in resistance training. In the first session of resistance training to become familiar and learn the correct movements, subjects with at least the first week submaximal weights and more reps, do. From the second week onwards, after estimating a repetition maximum (1RM) for each of the movements, exercises performed according to one repetition maximum. Resistance training involves 10 moves in a circular station is planned. Stations including: upper chest presses, shoulder presses (military) lat pull-down, leg press,leg extension, lying leg curl, calf raise, biceps and triceps is the wiring and sit-ups. 5 minutes is dedicated to cool.these values, people are allowed to participate in sports programs. An independent variable variables:

combined training two independent variables: the independent variable omega-3 supplement three: L - carnitine dependent variable: visfatin

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070328751N1**
Registration date: **2016-08-20, 1395/05/30**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-08-20, 1395/05/30

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Shahrood University of Technology

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effecf of 8-weeks combined exercise with omega-3 and l-carnitine supplement consumption on serum level visfatin in women with type 2 diabetes.

Public title

The effecf of exercise with omega-3 and l-carnitine supplement consumption in women with type 2 diabetes

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria Women with type 2 diabetes; according to the doctor at least three years past their diagnosis; blood sugar and blood pressure-lowering drugs blood glucose people only use blood fat. No change in blood glucose lowering drugs; blood fat and blood pressure in recent months, and should have blood pressure greater than 95/160 mm Hg. Exclusion criteria included insulin injections after the onset of the secondary complications of diabetes; such as protocol and having eye, kidney; diabetic foot ulcers and amputation and heart disease - cardiovascular; and inflammation.

Age

From **40 years** old to **64 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahrood University of Medical Sciences

Street address

Shahrood University of Medical Sciences, squre 7 tir, Shahrood, Semnan

City

Shahrood

Postal code

Approval date

2016-06-22, 1395/04/02

Ethics committee reference number

ir.shmu.rec.1395.56

Health conditions studied

1

Description of health condition studied
Diabetes type 2
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
visfatin
Timepoint
pretest: postest 8week
Method of measurement
serum

Secondary outcomes

1

Description
FBS
Timepoint
Pretest:postest 8 week
Method of measurement
srum

2

Description
TG
Timepoint
pretest: postest 8 week
Method of measurement
Serum

3

Description
TC
Timepoint
pretest: postest 8 week
Method of measurement
Serum

4

Description
Ensoline
Timepoint
pretest: postest 8 week
Method of measurement
Serum

5

Description
LDL
Timepoint
pretest: postest 8 week
Method of measurement
Serum

6

Description
HDL
Timepoint
pretest: postest 8 week
Method of measurement
Serum

7

Description
Insulin resistance
Timepoint
pretest: postest 8 week
Method of measurement
formola

Intervention groups

1

Description
exercise+l-carnitine
Category
Treatment - Drugs

2

Description
omega3+l-carnitine
Category
Treatment - Drugs

3

Description
exercise+pelasebo
Category
Treatment - Drugs

4

Description
control
Category
Treatment - Drugs

5

Description
exercise+omega3
Category
Treatment - Drugs

6

Description
exercise+omega3+l-carnitine

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahrood Diabetes Association
Full name of responsible person
Dr Hassani Behzad
Street address
Unit 5, 1 Floor, Amiralmomenin Medical Building, Shahid Mazji Street, 22 Bahman Street, Shahrood
City
Shahrood

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research,Shahrood University Of Technology
Full name of responsible person
Dr Dastfan Ali
Street address
Shahrood University Of Technology, Daneshgah Boolvar, Shahrood
City
Shahrood
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,Shahrood University Of Technology
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

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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