

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of L-carnitine supplementation on metabolic status, leptin and visfatin adipokines in obese diabetic women with hypocaloric diet

Protocol summary

Summary

Obesity and diabetes are two important health problems in the world. There is relationship between obesity and diabetes, probability of diabetes and metabolic syndrome in obese people, are more likely to occur. Diabetes and obesity are associated with such frequency that it has been proposed for the term Diabesity. So, decrease in adipose tissue could lead to a reduction in inflammatory markers, components of metabolic syndrome and increased insulin sensitivity is improved. In this double blind clinical trial we aim to achieve new approach for prevent and combat obesity and diabetes, sixty non pregnant or lactating premenopausal obese women aged 18 -48 years, with type 2 diabetes attending the Diabetes Clinic of Tabriz Red Crescent, who have not participated in weight-reduction programs during last 6 months, will be enrolled. Patients who don't follow the prescribed diet or using insulin and special diet or drugs or supplementes (such as vitamin B6, C) will be excluded from the study. Volunteers will be randomly allocated into two groups for 8 weeks intervention: Carnitine (1 gr, twice daily), with hypo caloric diet as an intervention group and placebo with hypo caloric diet as a control group. Inflammatory indicators (hs-CRP, IL-6), metabolic status (fasting blood sugar, insulin resistance, lipid profile), leptin, visfatin, anthropometric indicators and Body Fat mass will be measured at baseline and endpoint of study and will be analyzed statistically.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903164105N1**
Registration date: **2011-12-10, 1390/09/19**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-10, 1390/09/19

Registrant information

Name

Beit Allah Alipour

Name of organization / entity

Health & Nutrition Faculty

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 7580

Email address

alipourb@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Tabriz University Of Medical Sciences

Expected recruitment start date

2011-11-22, 1390/09/01

Expected recruitment end date

2011-12-22, 1390/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of L-carnitine supplementation on metabolic status, leptin and visfatin adipokines in obese diabetic women with hypocaloric diet

Public title

Effect of L-carnitine supplementation on metabolic status, leptin and visfatin adipokines in obese diabetic women with hypocaloric diet

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: obese women with type2 diabetic; age range 18 to 48years; no cancer, liver or renal disease; receiving any therapeutic diet except diabetes diet; no Pregnancy, lactation and menopause of women.

Exclusion criteria: Consumption of any food supplement or drug which influence carnitine or lipid profile (such as vitamin B6 - C); treatment with insulin and Failure to follow the prescribed diet.

Age

From **18 years** old to **48 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht ST, Tabriz +00984113357313

City

Tabriz

Postal code

Approval date

2011-10-17, 1390/07/25

Ethics committee reference number

5876/4/5

Health conditions studied

1

Description of health condition studied

Diabetic

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

2

Description of health condition studied

Obesity

ICD-10 code

E66

ICD-10 code description

obesity

Primary outcomes

1

Description

leptin

Timepoint

baseline, endpoint

Method of measurement

Elisa

2

Description

visfatin

Timepoint

baseline, endpoint

Method of measurement

Elisa

3

Description

Anthropometric indicators: weight, body mass index, waist circumference, hip circumference and waist to hip ratio

Timepoint

baseline, endpoint

Method of measurement

Standard procedures using scale, tape and equations

4

Description

Body Fat Mass

Timepoint

baseline, endpoint

Method of measurement

Bioimpedance

Secondary outcomes

1

Description

FBS

Timepoint

baseline, endpoint
Method of measurement
autoanalyzer

2

Description
Insulin resistance: Insulin, HOMA-IR index
Timepoint
baseline, endpoint
Method of measurement
Elisa and formula

3

Description
IL-6, hs-CRP
Timepoint
baseline, endpoint
Method of measurement
Elisa and autoanalyzer

4

Description
TG
Timepoint
baseline, endpoint
Method of measurement
autoanalyzer

5

Description
cholesterol
Timepoint
baseline, endpoint
Method of measurement
autoanalyzer

6

Description
HDL
Timepoint
baseline, endpoint
Method of measurement
autoanalyzer

7

Description
blood pressure
Timepoint
baseline, endpoint
Method of measurement
sphygmomanometer

Intervention groups

1

Description

Intervention groups: 1 gr of carnitine tablet twice a day with hypocaloric diet (500 kcal less than patients's energy requirements)

Category

Treatment - Drugs

2

Description
Control groups: 1 gr of placebo twice a day with hypocaloric diet (500 kcal less than patients's energy requirements)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Tabriz Red Crescent

Full name of responsible person

Ali Barzegar

Street address

Tabriz Red Crescent, Abrasan Ave, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research, Tabriz University Of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Rashidi, Dr.Alireza Ostadrahimia

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Tabriz University of Medical Sciences, Golgasht ST,Tabriz +00984113357313

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Tabriz

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, Tabriz 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

School of Health and Nutrition, Tabriz university of Medical Sciences

Full name of responsible person

Dr. Beit Allah Alipour

Position

Assistant Professor of Nutrition, in School of Health and Nutrition

Other areas of specialty/work

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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