Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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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 requirementes)
Category
Treatment - Drugs

2

Description
Control groups: 1 gr of placebo twice a day with hypocaloric diet (500 kcal less than patients's energy requirementes)
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
Street address
Tabriz University of Medical Sciences, Golgasht ST,Tabriz +00984113357313
City
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 Mdical 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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Ali Barzegar

Position
Ph.D student in Nutrition

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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