

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of vitamins E and C on the serum levels of leptin and inflammation factors in type II diabetic patients

Protocol summary

Summary

Leptin, an adipose tissue hormone, is a potential link between insulin resistance and type 2 diabetes in rodent. In humans, the role of Leptin in regulating insulin resistance and type 2 diabetes is also unclear. In this study we investigated the effects of vitamin C and vitamin E on serum levels of Leptin and HOMA-IR in 120 type 2 diabetic patients in pre and post case control study. Inclusion criteria include of patients who had type 2 diabetes and Exclusion criteria include of patients who had liver diseases, Kidney disease, Hypo- or Hyper-thyroidism or used to vitamin C and E, were excluded from the study . This clinical trial study consisting of 40 patients with type 2 diabetes who has received 1000 mg vitamin C as vitamin C group and 40 patients with type 2 diabetes who has received 400 IU vitamin E as vitamin E group and 40 patients with type 2 diabetes who has not received any things as a control group for 4 weeks. Before and after intervention glucose ,profile lipids ,insulin,hs-CRP, HOMA-IR and serum Leptin in three groups were measured by standard method. The results were analyzed by students T-test and Anova.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202208025N3**

Registration date: **2012-03-14, 1390/12/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-03-14, 1390/12/24

Registrant information

Name

Mohammad Ali Ghaffari

Name of organization / entity

Ahwaz Joundishapour University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research(Research and Technology),
Ahwaz Jondishapur University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2011-10-23, 1390/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamins E and C on the serum levels of leptin and inflammation factors in type II diabetic patients

Public title

The effect of vitamins E and C on the serum levels of leptin and inflammation factors in type II diabetic patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients who had type 2 diabetes.

Exclusion criteria: Patients who had liver diseases;

Kidney disease; Hypo- or Hyper- thyroidism; myocard

infraction or blood disorders and used to drugs containing estrogen; progesterone; Diuretics; lower blood pressure and vitamin C and E; were excluded from the study

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

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**

Ethics Committee Ahwaz Jondishapur University of Medical Sciences

Street address

Ethics Committee Ahwaz Jondishapur University of Medical Sciences

City

Ahwaz

Postal code

6135715794

Approval date

2011-02-26, 1389/12/07

Ethics committee reference number

ETH-133

Health conditions studied**1****Description of health condition studied**

Diabetic mellitus 2

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

Leptin

Timepoint

Before and one month after the intervention

Method of measurement

by ELIZA method (ng/ml)

Secondary outcomes**1****Description**

Cholestrol

Timepoint

Before and one month after the intervention

Method of measurement

Autoanalyzer (mg/dl)

Intervention groups**1****Description**

GROUP 1: consumption of 1000 mg of vitamin C per day for 4 weeks

Category

Prevention

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

Golestan Hospital

Full name of responsible person

Ashraf Azizollahi

Street address

Golestan Hospital next to Diabetes Research Center, Ahwaz Jondishapur University of Medical Sciences, Shahre Daneshgahi,

City

Ahwaz

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

Vice chancellor for research (Research and technology), Ahwaz Jondishapur University of Medical Sc

Full name of responsible person

Dr. Mostafa Feghi

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Postbox 45, Postcode 6135715794, Vice chancellor

for research(Research and technology), Ahwaz
Jondishapur University of Medical Sciences, Shahre
Daneshgahi,

City

Ahwaz

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 (Research and technology),Ahwaz Jondishapur University of Medical Sc

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

Name of organization / entity

Ahwaz Jondishapur University of Medical Sciences

Full name of responsible person

Mozhgan Noor Behbahani

Position

Expert of Laboratory Sciences

Other areas of specialty/work

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Mozhgan Noor Behbahani

Position

Expert of Laboratory Sciences

Other areas of specialty/work

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Web page address

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