

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 1337 7192

##### Email address

ghaffari@ajums.ac.ir

##### 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**

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**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

**Street address**

Postbox 45, Postcode 6135715794, Vice chancellor

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

**City**

Ahwaz

**Grant name**

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**Grant code / Reference number**

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**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**

**Street address**

Department of Biochemistry,School of  
Medicine,Ahwaz Jondishapur University of Medical  
Sciences, Shahre Daneshgahi,

**City**

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**Person responsible for scientific  
inquiries**

**Contact**

**Name of organization / entity**

cellular and molecular research center

**Full name of responsible person**

Mohammad Ali Ghaffari

**Position**

Biochemistry Ph.D.

**Other areas of specialty/work**

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Ahwaz Jondishapur University of Medical Sciences,  
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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Ahwaz Joundishapur 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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+98 61 1333 2036

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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*