

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of Omega3 on serum Visfatin concentration in patients with type 2 diabete.

#### Protocol summary

##### Summary

Visfatin is an adipocytokines which is secreted from adipose tissue and can be effective on the diabetes inflammatory reaction and also serum lipids level. On the other hand, Omega-3 can reduce the fats and also can prevent form insulin resistance. In the present study, the effect of Omega-3 on the serum visfatin concentration compared with placebo has been reviewed. A total of seventy-one women with type II diabetes in two groups had been under the treatment with Omega-3 capsules and the control group with placebo capsules. In the first step, the study subjects filled in a questionnaire including age, height, weight, waist circumference, hip circumference; besides, their blood sample were taken for the blood tests. In the second step, the intervention was done for 8 weeks and in the third step the above mentioned data and also blood sample were received again. Hip circumference was measured from the middle and the largest part of it and waist circumference also from the cord at the end of a normal exhalation. In the blood samples, the following parameters were measured: visfatin and lipid profiles (LDL: low density lipoprotein, HDL: high density lipoprotein, TG: triglyceride and cholesterol), glucose and HbA1c via a special measuring kit.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT138903164109N1**

Registration date: **2011-06-03, 1390/03/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-06-03, 1390/03/13

#### Registrant information

##### Name

Hossein Hajianfar

##### Name of organization / entity

Tehran Medical Science University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1951 3172

##### Email address

hajianfar@razi.tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tehran University of Medical Sciences

#### Expected recruitment start date

2009-09-23, 1388/07/01

#### Expected recruitment end date

2009-11-22, 1388/09/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of Omega3 on serum Visfatin concentration in patients with type 2 diabete.

#### Public title

Effect of Omega3 on serum Visfatin concentration

#### Purpose

Basic scienece

#### Inclusion/Exclusion criteria

Inclusion criteria: type II diabetic women with at least five years past from their diagnosis; women who were volunteers for participating in the study. Exclusion criteria: insulin injection, secondary complications of diabetes such as ophthalmic and renal complication,

amputation, diseases caused by diabetes complications such as kidney disease, amputation, blindness, heart diseases, and inflammatory disease in which CPR level was +++ or more.

#### Age

From **45 years** old to **65 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **71**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

N/A

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Tehran Medical Science University

##### Street address

Enghelan St 16 Azar

##### City

Tehran

##### Postal code

8143873333

#### Approval date

2008-04-10, 1387/01/22

#### Ethics committee reference number

10160

## Health conditions studied

### 1

#### Description of health condition studied

diabetes

#### ICD-10 code

E11

#### ICD-10 code description

non-insulin-dependent

## Primary outcomes

### 1

#### Description

Visfatin

#### Timepoint

befor and after trial

#### Method of measurement

special Lab kit

## Secondary outcomes

### 1

#### Description

TG

#### Timepoint

befor and after intervention

#### Method of measurement

pars azmoon kit

### 2

#### Description

HbA1c

#### Timepoint

befor and after intervention

#### Method of measurement

pars azmoon kit

### 3

#### Description

Cholestrol

#### Timepoint

befor and after intervention

#### Method of measurement

pars azmoon kit

### 4

#### Description

FBS

#### Timepoint

befor and after intervention

#### Method of measurement

pars azmoon kit

### 5

#### Description

HDL

#### Timepoint

befor and after intervention

#### Method of measurement

pars azmoon kit

### 6

#### Description

LDL

#### Timepoint

before and after intervention  
**Method of measurement**  
pars azmoon kit

## Intervention groups

### 1

#### Description

2 Omega3 capsules a day (1000 mg oil include 360 mg EPA and 240 mg DHA)

#### Category

Prevention

### 2

#### Description

2 Placebo Capsules a day (1gr corn starch)

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Institute Of diabetes charity Isfahan

##### Full name of responsible person

Dr Ali Kachoi

##### Street address

St Neshat 3rd floor of Javad alaema

##### City

Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran Medical Science University

##### Full name of responsible person

Dr MJ Hosseinzadeh

##### Street address

Enghelab sq,16 Azar st, Tehran

##### City

Tehran

#### Grant name

0

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tehran Medical Science University

#### 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

Tehran University of Medical Sciences

##### Full name of responsible person

Hossein Hajianfar

##### Position

MSc Student

##### Other areas of specialty/work

##### Street address

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##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr MJ Hosseinzadeh

##### Position

MD&PhD

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## Person responsible for updating data

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Tehran University of Medical Sciences

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Hossein Hajianfar

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**Fax****Email**

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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*