

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Sep 2023

### The Effect of Supplementation with Spirulina Platensis Algae on Serum Vascular Endothelial Growth Factor (VEGF) and Lipid Profile in Obese Individuals

#### Protocol summary

##### Summary

1-Objectives: The effect of supplementation with Spirulina Platensis algae on serum vascular endothelial growth factor (VEGF) and lipid profile in obese individuals  
2-Design: Double blinded randomized clinical trial  
3-Setting and conduct: The individuals will enter the intervention by public call. Individuals would be divided into two groups of intervention and control, each one including 32 people and matched by age and sex. The participants would be asked not to make change in their diet and physical activity during the supplementation. At the beginning of intervention, the participants will fill the general information questionnaire and anthropometric assessment would be performed for them. To execute biochemical tests, 7 cc of venal blood would be taken from the individuals before the trail and after 12 weeks of supplementation. The serum status of VEGF and lipid profile would be assessed at the beginning of trail and after 12 weeks of supplement usage. 24 hour recall questionnaire would be completed for 3 days of week and the end of intervention. 4-Participants: Obese people with BMI  $\geq 30$  kg/m<sup>2</sup> and in the age group of 20 to 50 who tend to co-operate in this research. 5-Intervention: 2 groups of intervention (receiver of Spirulina Platensis 500 mg tablet supplement for 12 weeks and 2 times a day) and control (receiver of placebo 500 mg tablet including starch with the same appearance of Spirulina supplement for 12 weeks and 2 times a day) each group including 32 people  
6-Main outcome: 1- Serum status of vascular endothelial growth factor (VEGF) 2-serum lipid profile

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015071219082N7**

Registration date: **2015-09-12, 1394/06/21**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-09-12, 1394/06/21

##### Registrant information

###### Name

Mahdieh Abbasalizad Farhangi

###### Name of organization / entity

Department of Community Nutrition School of Nutrition

###### Country

Iran (Islamic Republic of)

###### Phone

+98 413357580

###### Email address

abbasalizadm@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2015-07-23, 1394/05/01

##### Expected recruitment end date

2015-10-23, 1394/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Supplementation with Spirulina Platensis Algae on Serum Vascular Endothelial Growth Factor (VEGF) and Lipid Profile in Obese Individuals

### Public title

The Effect of Supplementation with Spirulina Algae on Growth Factor (VEGF) and Lipid Profile in Obese Individuals

### Purpose

Treatment

### Inclusion/Exclusion criteria

Inclusion criteria: tendency to attend; obese individuals with BMI  $\geq 30$  kg/m<sup>2</sup>; age group of 20 to 50. Exclusion criteria: history of renal disease; history of CVD; cancers; acute infections; recent surgeries; usage of weight effective drugs (hormone drugs); antidepressant drugs; diuretic drugs; antibiotics; glucocorticoids; usage of any supplements in the past 3 months; pregnancy; breast feeding; menopause; following weight loss diets in 3 months before and during the intervention.

### Age

From **20 years** old to **50 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **64**

### 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 Nutrition Faculty, Tabriz University of Medical Sciences

##### Street address

Nutrition Faculty, Tabriz University of Medical Sciences, Attar Street, Golgasht Street, Tabriz

##### City

Tabriz

##### Postal code

#### Approval date

2015-09-01, 1394/06/10

## Ethics committee reference number

TBZMED.REC.1494.4.61

## Health conditions studied

### 1

#### Description of health condition studied

obesity

#### ICD-10 code

E66.9

#### ICD-10 code description

obesity,unspecified

## Primary outcomes

### 1

#### Description

Serum vascular endothelial growth factor

#### Timepoint

Before the intervention, 12 weeks after the intervention

#### Method of measurement

ELISA

### 2

#### Description

Serum lipid profile

#### Timepoint

Before the intervention, 12 weeks after the intervention

#### Method of measurement

spectrophotometry,immunoturbidimetry

## Secondary outcomes

### 1

#### Description

Energy intake, Macronutrients

#### Timepoint

Before the intervention, 12 weeks after the intervention

#### Method of measurement

24 hours recall questionnaire

## Intervention groups

### 1

#### Description

Intervention group spirulina platensis algae supplement 500 mg, 2 tablets a day, during 12 weeks of intervention

#### Category

Treatment - Other

### 2

#### Description

Control group, placebo: 500 mg tablet containing starch with the same appearance of the Spirulina supplement, 2 times daily for 12 weeks

**Category**

Treatment - Drugs

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

Nik laboratory

**Full name of responsible person**

Hamidreza Hodjatzadeh

**Street address**Nik laboratory, Mellat Square, Northern Ostad Hasan  
Banna Street, Tehran**City**

Tehran

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Vice chancellor for research, Tabriz University of  
Medical sciences**Full name of responsible person**

Dr Alireza Ostad Rahimi

**Street address**Nutrition Faculty, Tabriz University of Medical  
Sciences, AttarSstreet, Golgasht Street, Tabriz**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****Name of organization / entity**Nutrition faculty, Tabriz University of Medical  
Sciences**Full name of responsible person**

Dr Mahdieh Abbasalizad Farhangi

**Position**

faculty member

**Other areas of specialty/work****Street address**Nutrition faculty, Tabriz University of Medical  
Sciences, Attar Street, Golgasht Street, Tabriz**City**

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Dr Mahdieh Abbasalizad Farhangi

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Ph.D

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**Web page address****Person responsible for updating data****Contact****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*