

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 ≥ 30 kg/m² 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

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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 ≥ 30 kg/m²; 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 addressNik 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 addressNutrition Faculty, Tabriz University of Medical
Sciences, AttarStreet, 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 sourceVice 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

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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*