

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The Effect of Spirulina Platensis Algae Supplementation on Serum Concentration Macrophage Inhibitory Cytokine (MIC-1), Superoxide Dismutase (SOD) and Glutathione Peroxidase (GPX) and Appetite in Obese Individuals

Protocol summary

Summary

Current study is performed in double blinded randomized clinical trial method in two groups of intervention and control with the aim of analyzing the effect of supplementation with Spirulina Platensis algae on serum status of Macrophage Inhibitory Cytokine-1 (MIC-1), Superoxide Dismutase (SOD) and Glutathione Peroxidase (GPX) and appetite in obese individuals. The obese individuals with BMI >30 kg/m² and age range of 20 to 50 years will form the statistical society. Qualified individuals will enter the trial by public call. The aim and method of the study would be explained to them. After filling out the consent, individuals would be divided into two groups of intervention (recipient of two 500 mg Spirulina Platensis tablets daily) and placebo, each one including 32 people. The intervention group will consume 2 tablets of Spirulina Platensis and the control group will consume 2 tablets of placebo with the same appearance daily for 12 weeks. The attendance will be matched by age and sex. They will be asked to not to change their diet and physical activity during the supplementation. At the beginning of the study, the attendance will fill out the general information questionnaire and anthropometric assessments will be done for them. To carry out the biochemical assessment, 7 cc of venal blood will be depleted before the trial and after 12 weeks. The status of studied factors will be assessed at the beginning of the trial and 12 weeks after supplementation. 24 hours recall for 3 days of a week will be completed as well. They would be asked about consumption of the tablets once a week.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071619082N8**

Registration date: **2015-09-30, 1394/07/08**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-09-30, 1394/07/08

Registrant information

Name

Mahdieh Abbasalizad Farhangi

Name of organization / entity

Department of Community Nutrition School of Nutrition

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2015-10-02, 1394/07/10

Expected recruitment end date

2015-12-31, 1394/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Spirulina Platensis Algae Supplementation on Serum Concentration Macrophage Inhibitory Cytokine (MIC-1), Superoxide Dismutase (SOD) and Glutathione Peroxidase (GPX) and Appetite in Obese Individuals

Public title

The Effect of Spirulina Algae on Inflammation Status and Appetite in Obese Individuals

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Tendency to attend the trial; BMI in the range of 30-39 kg/m²; age limit between 20 and 50 of years. Exclusion criteria: History of GI disease, diabetes, infections, cancers and drug therapy; consumption of any antioxidant multi-vitamins, fiber and Omega 3 supplements 3 months before and during the trial; pregnancy and breast feeding; menopause; following weight loss diets 3 months before and during the trial; history of renal diseases, CVD and recent surgeries; consumption of weight effective drugs (hormones and antidepressant drugs), diuretics, antibiotics; effective drugs on inflammation status.

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

Tabriz University of Medical Sciences, Health and Nutrition Faculty

Street address

Health and Nutrition Faculty, Attar Street, Golgasht Street, Tabriz

City

Tabriz

Postal code

Approval date

2015-08-16, 1394/05/25

Ethics committee reference number

TBZMED.REC.1394.429

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 Concentraion of Macrophage Inhibitory Cytokine-1 (MIC-1)

Timepoint

Before the intervention, 3 months after the intervention

Method of measurement

ELISA, pg/ml

2

Description

Superoxide Dismutase (SOD) status

Timepoint

Before the intervention, 3 months after the intervention

Method of measurement

Spectrophotometry, U/ml

3

Description

Glutathione Peroxidase (GPX) status

Timepoint

Before the intervention, 3 months after the intervention

Method of measurement

Spectrophotometry, Mu/ml

4

Description

Anthropometric parameters

Timepoint

Before the intervention, 3 months after the intervention

Method of measurement

Weight, kg; Height, cm

5

Description

Appetite

Timepoint

Before the intervention, 3 months after the intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Energy intake, macronutrients

Timepoint

Before the intervention, 3 months after the intervention begins

Method of measurement

Questionnaire

2

Description

Physical activity

Timepoint

Before the intervention, 3 months after the intervention begins

Method of measurement

Questionnaire

Intervention groups

1

Description

Supplement group: Spirulina Platensis Algae supplement 500 mg, 2 tablets a day, during 12 weeks of intervention.

Category

Treatment - Other

2

Description

Placebo: The same az supplement in appearance, without chlorophyll, 500 mg, 2 tablets a day, during 12 weeks of intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sohrabali Bakhshi Public Health Center

Full name of responsible person

Street address

City

Shahriar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Science

Full name of responsible person

Dr Alireza Ostad Rahimi

Street address

Attar Street, 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

Tabriz University of Medical Science

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

Health and Nutrition Faculty of Tabriz University of Medical Science

Full name of responsible person

Atefeh Shariat

Position

ms student

Other areas of specialty/work

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Name of organization / entity

Tabriz Medical Science University Health and Nutrition Faculty

Full name of responsible person

Dr Mahdieh Abbasalizad Farhangi

Position

Phd

Other areas of specialty/work**Street address**

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abbasalizadm@tbzmed.ac.ir

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