Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effects of Spirulina supplementation on anthropometric measurements, blood lipid profile, appetite, liver enzymes, inflammatory and glycemic markers in overweight or obese adults

Protocol summary

Summary

Objective: assessing the effects of Spirulina supplementation on anthropometric measurements, blood lipid profile, appetite, liver enzymes, inflammatory and glycemic markers in overweight or obese adults. Study design: in this double-blind Randomized Controlled Clinical Trial, Participants will be allocated to Spirulina or Placebo group through Blocked Randomization. Study population: obese and overweight subjects visiting nutrition clinic of Shahid Beheshti University of Medical Sciences. Sample size: fifteen subjects. Intervention: subjects in Spirulina group will consume 2 g Spirulina daily (four tablets of 500mg), whereas the control group receive placebo tablets during 12 weeks of intervention. In addition, subjects receive weight reduction diet during the study period. Outcome measures: anthropometric measurements (body weight, waist and hip circumference, BMI, body composition), inflammatory markers (hs- CRP and adiponectin), glycemic markers (fasting blood glucose and HOMA-IR), lipid profile (triacylglyceride, total cholesterol, LDL-C, HDL-C, LDL-C/HDL-C), liver enzymes (SGOT and SGPT) and appetite.

General information

Acronym

BMI: Body Mass Index, HOMA-IR: Homeostatic Model Assessment- Insulin Resistance, hs- CRP: High sensi

IRCT registration information

IRCT registration number: **IRCT2016101615968N4**
Registration date: **2017-01-04, 1395/10/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-01-04, 1395/10/15

Registrant information

Name

Atoosa Saidpour

Name of organization / entity

Shahid Beheshti University of Medical Sciences, School of nutrition

Country

Iran (Islamic Republic of)

Phone

-

Email address

a.saidpour@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Nutrition department of Shahid Beheshti University of Medical sciences

Expected recruitment start date

2014-11-06, 1393/08/15

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Spirulina supplementation on anthropometric measurements, blood lipid profile, appetite, liver enzymes, inflammatory and glycemic markers in overweight or obese adults

Public title

Effects of Spirulina supplementation on obese patients

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: aged 20-60 years old, 40 kg/m2 >BMI>25 kg/m2, no history of medications for obesity, diabetes, dyslipidemia, inflammatory diseases and vitamin supplementation within 3 months before the study Exclusion criteria: having chronic kidney or hepatic disease except NAFLD, hypo or hyperthyroidism, autoimmune and infectious disease, weight reduction diet therapy within 6 month, more than 3 kg weight change in recent 2 months and recent surgery, taking anticoagulant medications the same as warfarin or aspirin, pregnancy and lactation

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
In order to run a double- blind survey, in the beginning the bottle of Spirulina and placebo tablets were labeled as A or B by someone other than the researchers. So, both researchers and patients will be unaware of the type of received tablets.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical sciences

Street address
No. 7, Hafezi (Arghavan) St., Farahzadi Ave., Shahrake Ghods(Gharb) town, Tehran, Iran

City
Tehran

Postal code
1981619573

Approval date
2016-10-10, 1395/07/19

Ethics committee reference number
IR.sbmu.nnftri.Rec.1395.63

Health conditions studied

1

Description of health condition studied
obesity

ICD-10 code
E-66, E-65

ICD-10 code description
Obesity, Localized adiposity

Primary outcomes

1

Description
Body weight

Timepoint
before intervention, after 6 weeks of intervention and after 12 weeks of intervention

Method of measurement
seca scale

2

Description
BMI

Timepoint
before intervention, after 6 weeks of intervention and after 12 weeks of interventionbefore intervention

Method of measurement
calculation (kg/m2)

3

Description
waist circumference

Timepoint
before intervention, after 6 weeks of intervention and after 12 weeks of intervention

Method of measurement
metere

4

Description
Hip circumference

Timepoint
before intervention, after 6 weeks of intervention and after 12 weeks of intervention

Method of measurement
metere

5

Description
waist/hip

Timepoint
before intervention, after 6 weeks of intervention and after 12 weeks of intervention

Method of measurement
calculation

6

Description
Body fat mass
Timepoint
before intervention, after 6 weeks of intervention and after 12 weeks of intervention
Method of measurement
Bioelectrical impedance analysis (BIA) device

7

Description
Body fat free mass
Timepoint
before intervention, after 6 weeks of intervention and after 12 weeks of intervention
Method of measurement
Bioelectrical impedance analysis (BIA) device

8

Description
Appetite
Timepoint
before intervention, after 6 weeks of intervention and after 12 weeks of intervention
Method of measurement
simple appetite questionnaire

9

Description
Serum adiponectin
Timepoint
Before intervention and after 12 weeks of intervention
Method of measurement
ELISA

10

Description
Serum hs-CRP
Timepoint
Before intervention and after 12 weeks of intervention
Method of measurement
ELISA

Secondary outcomes

1

Description
serum triacylglycerol
Timepoint
before intervention and after 12 weeks of intervention
Method of measurement
Colorimetric enzymatic method (Pars Azmun)

2

Description
serum total cholesterol
Timepoint
before intervention and after 12 weeks of intervention
Method of measurement
Colorimetric enzymatic method (Pars Azmun)

3

Description
HDL-C
Timepoint
before intervention and after 12 weeks of intervention
Method of measurement
Colorimetric enzymatic method (Pars Azmun)

4

Description
LDL-C
Timepoint
before intervention and after 12 weeks of intervention
Method of measurement
Colorimetric enzymatic method (Pars Azmun)

5

Description
LDL-C/HDL-C
Timepoint
before intervention and after 12 weeks of intervention
Method of measurement
calculation

6

Description
srum glucose
Timepoint
before intervention and after 12 weeks of intervention
Method of measurement
Colorimetric enzymatic method (Pars Azmun)

7

Description
serum insulin
Timepoint
before intervention and after 12 weeks of intervention
Method of measurement
ELISA

8

Description
HOMA-IR
Timepoint
before intervention and after 12 weeks of intervention
Method of measurement
calculation ([Glucose]*[Insulin]/405(Glucose in mg/dl))

9

Description
serum SGOT
Timepoint

before intervention and after 12 weeks of intervention

Method of measurement

Colorimetric enzymatic method (Pars Azmun)

10

Description

serum SGPT

Timepoint

before intervention and after 12 weeks of intervention

Method of measurement

Colorimetric enzymatic method (Pars Azmun)

Intervention groups

1

Description

Intervention1: Daily intake of 2 g Spirulina as 4 tablets of 5oo mg for 3 months, weight reduction diet therapy simultaneously with Spirulina supplements for 12 weeks

Category

Treatment - Drugs

2

Description

Intervention 2: Daily intake of 4 placebo tablets for 12 weeks, weight reduction diet therapy concurrently with receiving placebo for 12 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinical Nutrition and Diet Therapy Clinic of Shahid Beheshti University of Medical Sciences

Full name of responsible person

Reyhaneh Yousefi

Street address

Baran St.,Hafezi (Arghavan) Ave., Farahzadi Blvd., Ghods (Gharb) twon, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fatemeh Mohammadi Nasrabadi

Street address

No. 7, Hafezi (Arghavan) st., Farahzdi Blvd., Ghods (Gharb) twon, Tehran, Iran

City

Tehran

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, Shahid Beheshti University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Ashbal Chemi Co.

Full name of responsible person

Maryam Soheili

Street address

Third floor, Abiasa bulding, Barforooshan St., Iranshahr Av., Tehran

City

Tehran

Grant name

تأمین کننده قرص های اسپیرولینا برای مطالعه

Grant code / Reference number

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

Yes

Title of funding source

Ashbal Chemi Co.

Proportion provided by this source

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

National Institute of Nutrition and Food Technology

Full name of responsible person

Rehaneh Yousefi

Position

MSc. student of Nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical sciences-School of Nutrition
Full name of responsible person
Atoosa Saidpour
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PHD of Nutrition
Other areas of specialty/work
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www.nnftri.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
National Institute of Nutrition and Food Technology
Full name of responsible person
Reyhaneh Yousefi
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MSc. student of Nutrition
Other areas of specialty/work
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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