Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 2026

The Effect of Chlorella Vulgaris Supplementation on Metabolic, Blood Pressure and Antropometric Indices on Non-alcoholic fatty liver disease (NAFLD) patients

Protocol summary

Summary

This randomized double blind placebo controlled trial design with aim to determine the effect of chlorella vulgaris supplementation on oxidative stress and inflammatory indices on non-alcoholic fatty liver disease (NAFLD) patients. 70 patients with NAFLD will be randomly divided into 2 intervention and placebo groups. Subjects in two intervention and placebo group will receive 4 tablets of chlorella vulgaris daily (each containing 300 mg, daily 1200 mg) or 4 tablets of placebo respectively for two month. For all of the participants, personality questionnaire and 3 dietary records (0,4.8 weeks) will be filled for assessment of nutrient intake and food frequency questionnaire for food habit evaluation. The anthropometric and biochemical measurements at first and end of the study will be repeated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012110911220N1**
Registration date: **2012-11-16, 1391/08/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-11-16, 1391/08/26

Registrant information

Name

Soodabeh Aliashrafi

Name of organization / entity

Student Research committee, Nutrition and Health faculty

Country

Iran (Islamic Republic of)

Phone

+98 41 1385 2090

Email address

aliashrafis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Student research committe, Health and Nutrition Faculty, Tabriz University of Medical Sciences

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2013-02-19, 1391/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Chlorella Vulgaris Supplementation on Metabolic, Blood Pressure and Antropometric Indices on Non-alcoholic fatty liver disease (NAFLD) patients

Public title

The Effect of Chlorella Vulgaris Supplementation on Metabolic, Blood Pressure and Antropometric Indices on Non-alcoholic fatty liver disease (NAFLD) patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Liver steatosis on sonographic image; 20-50 years old; BMI>=30; moderately activity.
Exclusion criteria: Alcohol intake more than 20g/d; gestation or lactation or Menopause; very active or

inpatients; Cardiovascular disease; Pulmonary disease; renal disease; liver transplantation; other liver diseases and chronic or acute liver disease(Hepatitis A,B, ...); bilious impairments; cancers; inheritance diseases; using drugs like, insulin sensitivity enhancer, hepatotoxic drugs and estrogen

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

Gender
Both

Phase
N/A

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Research Ethics Committee of Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences, Attar Neyshabori Street

City
Tabriz

Postal code

Approval date
2012-03-12, 1390/12/22

Ethics committee reference number
9129

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver disease

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Liver Enzyme (ALT,AST,ALP)

Timepoint
Beginning and end of the intervention

Method of measurement
IFCC

2

Description
Liver steatosis

Timepoint
Begining and end of intervention

Method of measurement
Liver Sonography

3

Description
FBS

Timepoint
Begining and end of intervention

Method of measurement
Enzymatic method

4

Description
TC, TG, LDL-C, HDL_c

Timepoint
Begining and end of intervention

Method of measurement
Enzymatic method forTC,TG and HDL-c for LDL-c:Freid wals formula

5

Description
Blood pressure

Timepoint
Begining and end of intervention

Method of measurement
Mercury manometer

6

Description
anthropometry

Timepoint
Begining and end of intervention

Method of measurement
Scale and meter

Secondary outcomes

1

Description
Energy and nutrient intake

Timepoint
beginning and end of the intervention
Method of measurement
Dietary record and food frequency questionnaire

Intervention groups

1

Description
Intervention Group: 300 mg chlorella vulgaris, 4 tablets/day for 8 weeks
Category
Treatment - Drugs

2

Description
Placebo groups: placebo, 4 tablets/day for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sheykholrais clinic
Full name of responsible person
Street address
City
Tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Ostadrahimi
Street address
Tabriz University of Medical Sciences, Attar Neyshabori Street, Golgasht Street
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 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
Student Serearch Committee, Nutrition and Health faculty,Tabriz university of medical sciences
Full name of responsible person
Soodabeh Aliashrafi
Position
Master Science Student of Nutrition
Other areas of specialty/work
Street address
Tabriz University of Medical Sciences, Attar Neyshabori Street, Golgasht Street
City
Tabriz
Postal code
Phone
+98 41 1334 1113
Fax
Email
Aliashrafis@tbzmed.ac.ir ; SA.NUY89@yahoo.com ; SAliashrafi@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Student research committe, Health and nutrition faculty, Tabriz University of Medical Sciences
Full name of responsible person
Soodabeh Aliashrafi
Position
Master Science Student of Nutrition
Other areas of specialty/work
Street address
Health and Nutrition Faculty,Tabriz University of Medical Sciences, Attar Neyshabori Street, Golgasht Street
City
Tabriz
Postal code
Phone
+98 41 1334 1113
Fax
Email
Aliashrafis@tbzmed.ac.ir ; SA.NUT89@yahoo.com ; SAliashrafi@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Student research committee, Tabriz University of

Medical Sciences, Health and nutrition faculty

Full name of responsible person

Soodabeh Aliashrafi

Position

Master Science Student of Nutrition

Other areas of specialty/work

Street address

Health and Nutrition Faculty,Tabriz University of Medical Sciences, Attar Neyshabori Street, Golgasht Street

City

Tabriz

Postal code

Phone

+98 41 1336 6581

Fax

Email

Aliashrafis@tbzmed.ac.ir ; SA.NUT89@yahoo.com ; SAliashrafi@gmail.com

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