

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Sep 2026

The Effect of Chlorella Vulgaris Supplementation on Oxidative Stress and Inflammatory 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: **IRCT201202233320N7**
Registration date: **2012-05-04, 1391/02/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-05-04, 1391/02/15

Registrant information

Name

Mehrangiz Ebrahimi mamagani

Name of organization / entity

Health & Nutrition faculty of Tabriz university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Nutritional Research Center, Health and Nutrition Faculty, Tabriz University of Medical Sciences

Expected recruitment start date

2011-12-31, 1390/10/10

Expected recruitment end date

2012-06-19, 1391/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Chlorella Vulgaris Supplementation on Oxidative Stress and Inflammatory Indices on Non-Alcoholic Fatty Liver Disease (NAFLD) Patients

Public title

The Effect of Chlorella Vulgaris Supplementation on Oxidative Stress and Inflammatory 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: **70**

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**

2012-04-16, 1391/01/28

Ethics committee reference number

5128

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**

Oxidative Stress Indices

Timepoint

Beginning and end of the intervention

Method of measurement

TAC and ARE spectrophotometry, SOD and Gpx by Spectrometry and MDA thiobarbituric acid

2**Description**

Inflammatory Indices

Timepoint

Beginning and end of the intervention

Method of measurement

TNF-α and hs-CRP measurement with special kits

3**Description**

Liver Enzyme (ALT,AST,ALP)

Timepoint

Beginning and end of the intervention

Method of measurement

IFCC

4**Description**

Liver steatosis

Timepoint

Beginning and end of the intervention

Method of measurement

Liver Sonography

Secondary outcomes**1****Description**

anthropometry

Timepoint

Begining and end of intervention

Method of measurement

Scale and meter

2**Description**

Energy and nutrient intake

Timepoint

beginning, fourth week 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

Sheykholarais 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

Nutritional Research Center, Health and nutrition faculty, Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mehrangiz Ebrahimimamagani

Position

Nutrition, PhD

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