Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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

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Name of organization / entity
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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 Indicies

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 Indicies

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
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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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