

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 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 committee, 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 $\geq$ 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**

Beginning and end of intervention

##### **Method of measurement**

Liver Sonography

#### **3**

##### **Description**

FBS

##### **Timepoint**

Beginning and end of intervention

##### **Method of measurement**

Enzymatic method

#### **4**

##### **Description**

TC, TG, LDL-C, HDL\_c

##### **Timepoint**

Beginning 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**

Beginning and end of intervention

##### **Method of measurement**

Mercury manometer

#### **6**

##### **Description**

anthropometry

##### **Timepoint**

Beginning 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**

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**

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**

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**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*