

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of Chlorella Vulgaris and Spirulina supplementation effect on oxidative stress, lipids profile and liver function in patients with Non-Alcoholic Fatty Liver

Protocol summary

Summary

The aim of this study is, making clear effect of Chlorella Vulgaris supplement and Spirulina supplement in patient by Non-Alcoholic Fatty Livers (NAFLD) and in case of observing beneficial effects, giving recommendation for taking these 2 supplements in to diet of such patients. In this Randomized clinical trial, without placebo control which is not blind, accidentally 72 patients (NAFLD) by counting 10% loss will be chosen. Age of participants is between 20-50 years by NAFLD which are approved by ultrasound. History of alcohol consumption and dyslipidemia who use drug and chronic disorders are some criterias for being out of this study. The participants are divided into three groups: Group 1, group 2, and group 3 known as control group. Group 1 receives a daily supplement of 1 gram Chlorella Vulgaris, group 2 is given a daily supplement of 1 gram of Spirulina and the control group does not receive any treatment. LDL, HDL, TG and total cholesterol, ALT, AST, ALP and oxidative stress index are examined at the beginning and the end of the study. Height, Weight, Waist Circumference, Blood Pressure and 24-hour recall of food are examined too of program. It will be requested from participants do not change physical activity, diet and lifestyle during accomplishment. Patients will be followed up by phone calls and face to face meeting duration of interference will be 8 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121620345N1**
Registration date: **2015-10-19, 1394/07/27**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-10-19, 1394/07/27

Registrant information

Name

Maryam Chitsazi J

Name of organization / entity

School of Public Health, Shahid Sadoughi University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 66 4253 3100

Email address

mchitsaz@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Yazd Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2014-12-20, 1393/09/29

Expected recruitment end date

2015-06-19, 1394/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Chlorella Vulgaris and Spirulina supplementation effect on oxidative stress, lipids profile and liver function in patients with Non-Alcoholic Fatty Liver

Public title

Comparison of two complementary prebiotics in the treatment of Non-Alcoholic Fatty Liver

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age range 20-50 years with NAFLD(Non-Alcoholic Fatty Liver) confirmed by ultrasound; have not participated in other research projects. Exclusion criteria: history of alcohol consumption; dyslipidemia who are taking medications; pregnancy and lactation; history of high blood pressure; lung disease; kidney disease; liver transplantation; complications of diabetes and chronic disorders that cause aggregation of fat in the liver such as diabetes; hepatitis use of some drugs: such as Tamoxifen; blood pressure control; statins; insulin sensitivity enhancers; hepatotoxic drugs; birth control pills and estrogen.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Yazd Shahid Sadoghi University of Medical Sciences
Ethics Committee

Street address

Yazd University of Medical Sciences, Bahonar Square,
Yazd

City

Yazd

Postal code

8916189165

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

17/1/164965/پ

Health conditions studied**1****Description of health condition studied**

Non-Alcoholic Fatty Liver

ICD-10 code

K75.8

ICD-10 code description

Non-Alcoholic Fatty Liver (Non-Alcoholic Steato Hepatitis)

Primary outcomes**1****Description**

Alanine Amino Transferase(ALT)

Timepoint

Before and after 8 weeks

Method of measurement

Method :IFCC (International Federation Clinical
Chemistry) , IU/L

2**Description**

Aspartate Amin Transferase (AST)

Timepoint

Before and after 8 weeks

Method of measurement

Method :IFCC (International Federation Clinical
Chemistry) , IU/L

3**Description**

Alkaline phosphatase (ALP)

Timepoint

Before and after 8 weeks

Method of measurement

Method :IFCC (International Federation Clinical
Chemistry) , IU/L

4**Description**

TG (Triglyceride)

Timepoint

Before and after 8 weeks

Method of measurement

Enzymatic (mg/dl)

5**Description**

TC (Total Cholesterol)

Timepoint

Before and after 8 weeks

Method of measurement

Enzymatic (mg/dl)

6

Description

LDL-C

Timepoint

Before and after 8 weeks

Method of measurement

Friedewald formula(mg/dl)

7

Description

HDL-C

Timepoint

Before and after 8 weeks

Method of measurement

Deposit method(mg/dl)

Secondary outcomes

1

Description

Serum Total Antioxidant Capacity (TAC)

Timepoint

Before and after 8 weeks

Method of measurement

the DPPH (Diphenyl-2-Picrylhydrazyl) percentage reduction

2

Description

Serum Malon Di Aldehyde (MDA)

Timepoint

Before and after 8 weeks

Method of measurement

based on Calorimetry

Intervention groups

1

Description

The intervention group will take 1 gram Spirulina (platensis) supplementation, at least one hour before the lunch meal with a glass of water, which is for 8 weeks. Supplementations containing Spirulina microalgae will be purchased of Ghesm Sina microalgae pharmaceutical company. Supplements will be delivered to patients every 4 weeks and the phone will be used during consumption and probable side effects of that.

Category

Treatment - Drugs

2

Description

The intervention group number daily will take 1 gram Chlorella Vulgaris supplement, at least one hour before the lunch meal with a glass of water for 8 weeks. Supplements include Chlorella microalgae will be

purchased from Ghesm Sina micro-algae pharmaceutical company. Supplements will be delivered to patients every 4 weeks and the phone will be using during consumption and probable side effects of taking it.

Category

Treatment - Drugs

3

Description

The control group did not receive the intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Shahid Sadoghi Hospital

Full name of responsible person

Salman Roghani Hasan, Gastroenterologist, Assistant Professor

Street address

Yazd Shahid Sadoghi Hospital, Ibn Sina Avenue, Shahid Ghandi Boulevard, Safaeieh, Yazd

City

Yazd

2

Recruitment center

Name of recruitment center

Dr Salman Roghani Hasan Office

Full name of responsible person

Salmanroghani Hasan, Gastroenterologist, Assistant Professor

Street address

Opposite the gas station, Montazer Ghaem Boulevard, Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Mehrpavar Houshang Amir

Street address

Vice Chancellor for Research, University Headquarters, Bahonar Square, Yazd

City

Yazd

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 Yazd Shahid Sadoughi 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**

School of Public Health, Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Chitsazi J Maryam

Position

Master of Sciences in Nutrition Health

Other areas of specialty/work**Street address**

School of Public Health, Pardis of Yazd University of Medical Sciences, Shahid Gomnam Boulevard, Hesabi Professor Blvd, Yazd

City

Yazd

Postal code

89165887

Phone

+98 353536240691

Fax**Email**

mahshid_chitsaz66@yahoo.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Yazd Sadoughi Shahid University of Medical Sciences

Full name of responsible person

Khosravi Mozaffari Hasan

Position

PHD of Nutrition

Other areas of specialty/work**Street address**

School of Public Health, Pardis of Yazd University of Medical Sciences, Shahid Gomnam Boulevard, Hesabi Professor Blvd, Yazd

City

Yazd

Postal code

89165887

Phone

+98 35 3624 0691

Fax**Email**

mozaffari.kh@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

School of Public Health, Yazd Sadoughi Shahid University of Medical Sciences

Full name of responsible person

Chitsazi J Maryam

Position

Master of Sciences in Nutrition Health

Other areas of specialty/work**Street address**

School of Public Health, Pardis of Yazd University of Medical Sciences, Shahid Gomnam Boulevard, Hesabi Professor Blvd, Yazd

City**Postal code****Phone**

+98 66 4253 3100

Fax**Email**

mahshid_chitsaz66@yahoo.com
mahshid_chitsaz66@yahoo.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