Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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 Gheshm Sina micro-algae 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 Gheshm 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 Boulvard, 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
Mehrparvar 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 Sadoghi 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 Sadoghi 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.commchitsaz.nut@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