Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 2026

Effect of phytosterols supplementation on serum levels of inflammatory markers ,liver enzymes ,lipid profiles ,Adiponectin ,Leptin and fasting blood sugar in non-alcoholic fatty liver disease patients

Protocol summary

Summary

The purpose of this study is to investigate the effect of phtosterol supplementation on serum levels of inflammatory markers, liver enzymes, leptin, adiponectin in patients with non alcoholic fatty liver disease. This Controlled, double-blind, randomized clinical trial will perform on 42 patients. Patients will randomly divide into 2 groups: The case and control group will receive phytosterols supplement (1.6 g per day) and starch (1.6 g per day) as placebo respectively, for 2 months. Variables including anthropometric indicators, blood pressure, inflammatory markers, liver enzymes, fasting blood sugar and lipid profile will measure before and after of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011531958N1**
Registration date: **2017-02-20, 1395/12/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-20, 1395/12/02

Registrant information

Name

mohammad ali javanmardi

Name of organization / entity

jondishapur university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3825 0550

Email address

javanmardi.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Ahvaz jondishapur University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of phytosterols supplementation on serum levels of inflammatory markers ,liver enzymes ,lipid profiles ,Adiponectin ,Leptin and fasting blood sugar in non-alcoholic fatty liver disease patients

Public title

effect of phytosterols on non alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 19-59 years old patient with non alcoholic fatty liver disease Exclusion criteria: Patients who have diabetes, cardiovascular, kidney and other hepatic diseases; Pregnant or lactating women; Smoking; Alcohol consumption; Use of dietary supplements

Age

From **19 years** old to **59 years** old

Gender

Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **42**
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
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Jondishapur University Of Medical Sciences, Golestan Ave. Ahvaz
City
ahvaz
Postal code
6165777696
Approval date
2017-02-12, 1395/11/24
Ethics committee reference number
IR.AJUMS.REC.1395.718

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
Aspartate aminotransferase
Timepoint
Before intervention and 2 months after intervention
Method of measurement
blood test

2

Description
Alanine aminotransferase
Timepoint
Before intervention and 2 months after intervention
Method of measurement
blood test

3

Description
Gamma-glutamyl transpeptidase
Timepoint
Before intervention and 2 months after intervention
Method of measurement
blood test

4

Description
Interlukine-6
Timepoint
Before intervention and 2 months after intervention
Method of measurement
blood test

5

Description
hs-CRP
Timepoint
Before intervention and 2 months after intervention
Method of measurement
blood test

6

Description
TNF-α
Timepoint
Before intervention and 2 months after intervention
Method of measurement
blood test

7

Description
Total cholestrol
Timepoint
Before intervention and 2 months after intervention
Method of measurement
blood test

8

Description
LDL-C
Timepoint
Before intervention and 2 months after intervention
Method of measurement
blood test

9

Description
HDL-C
Timepoint
Before intervention and 2 months after intervention
Method of measurement
blood test

10

Description
Triglyciride
Timepoint
Before intervention and 2 months after intervention
Method of measurement
blood test

11

Description
VLDL
Timepoint
Before intervention and 2 months after intervention
Method of measurement
TG/5

12

Description
Adiponectin
Timepoint
Before intervention and 2 months after intervention
Method of measurement
blood test

13

Description
Leptin
Timepoint
Before intervention and 2 months after intervention
Method of measurement
blood test

14

Description
Fasting blood sugar
Timepoint
Before intervention and 2 months after intervention
Method of measurement
blood test

Secondary outcomes

1

Description
Blood pressure
Timepoint
Before intervention and 2 months after intervention
Method of measurement
By manometer according to mmHg

2

Description
Body weight
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Digital scale

3

Description
Body mass index
Timepoint
Before intervention and 2 months after intervention
Method of measurement
Body weight in kilograms divided by height squared in meters

4

Description
Waist circumference
Timepoint
Before intervention and 2 months after intervention
Method of measurement
By measuring tape according to meter

5

Description
Hip circumference
Timepoint
Before intervention and 2 months after intervention
Method of measurement
By measuring tape according to meter

Intervention groups

1

Description
Intervention group : daily consumption of 400 mg phytosterols supplement (twice a day and each time 2 tabs=1.6 g) for 60 days
Category
Treatment - Drugs

2

Description
control group : daily consumption of 400 mg starch (twice a day and each time 2 tabs=1.6 g) for 60 days
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Gastroenterology Clinic of Golestan Hospital

Full name of responsible person

Street address

City
ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Ahvaz Jondishapur University Of Medical Sciences

Full name of responsible person
dr.nader saki

Street address
Ahvaz Jondishapur University Of Medical Sciences, Golestan Ave. Ahvaz

City
ahvaz

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, Ahvaz Jondishapur 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 Paramedicine, Ahvaz Jondishapur University Of Medical Sciences

Full name of responsible person
mohammad ali javanmardi

Position
Msc. in Nutrition sciences

Other areas of specialty/work

Street address
Ahvaz Jondishapur University of Medical Sciences, Golestan Ave. Ahvaz

City
ahvaz

Postal code

Phone
+98 61 3333 3050

Fax

Email
javanmardi.m@ajums.ac.ir//soroush.javanmardi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
School of Paramedicine, Ahvaz Jondishapur University of Medical Sciences

Full name of responsible person
dr.Majid Mohammadshahi

Position
PhD. in Nutrition sciences

Other areas of specialty/work

Street address
Ahvaz Jondishapur University of Medical Sciences, Golestan Ave. Ahvaz

City
ahvaz

Postal code

Phone
+98 61 3333 3050

Fax

Email
shahi334@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
School of Paramedicine, Ahvaz Jondishapur University of Medical Sciences

Full name of responsible person
mohammad ali javanmardi

Position
Msc. in Nutrition Sciences

Other areas of specialty/work

Street address
Ahvaz Jondishapur University of Medical Sciences, Golestan Ave. Ahvaz

City
ahvaz

Postal code

Phone
00

Fax

Email
javanmardi.m@ajums.ac.ir//soroush.javanmardi@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