

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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 phytosterol 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

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Name of organization / entity

jondishapur university of medical sciences

Country

Iran (Islamic Republic of)

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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 cholesterol

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

Triglyceride

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

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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