

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of chitosan supplementation on changes of weight, glycemic risk factors, lipid profile, serum inflammatory factors, adipokines and total antioxidant capacity in patients with nonalcoholic fatty liver disease (NAFLD)

Protocol summary

Study aim

The effect of chitosan supplementation on changes of weight, glycemic risk factors, lipid profile, serum inflammatory factors, adipokines and total antioxidant capacity in patients with nonalcoholic fatty liver disease (NAFLD)

Design

A clinical trial with control group (n=50), with parallel groups, double blind, randomized

Settings and conduct

This is a clinical trial study performed on Fatty liver patients referred to Golestan Hospital in 1397. The informed consent is given to the participants. Then, a 3-part questionnaire is completed by the subjects. Blood samples are collected at baseline and 12 weeks after the study. Study participants, the main researcher, the specialist, the person who collects the data and analyzes the outcomes are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals aged between 18-65 years of both genders; diagnosis of nonalcoholic fatty liver disease by ultrasound; willingness to participate
Exclusion criteria: Suffering from other kinds of liver disease, diseases that involves bile ducts, hypothyroidism, lipodystrophy, ; history of chronic liver disease, cardiovascular and renal disease; history of significant weight loss (more than 10% of body weight during 6 months ago) or weight loss surgery; history of antioxidant supplementation, omega 3 and milk thistle during 6 months ago; history of liver damaging drug; history of; alcohol consumption more than 20 gram per day, pregnancy and lactation; menopause; energy consumption less than 800 or more than 4200 kilocalorie per day

Intervention groups

Intervention group: patients with nonalcoholic fatty liver,

18 to 65 years, receiving chitosan supplements for 12 weeks
Control group: patients with nonalcoholic fatty liver, 18 to 65 years, receiving placebo for 12 weeks

Main outcome variables

glycated hemoglobin; fasting blood glucose; insulin; TNF- α ; IL-6; adiponectin; leptin; TAC

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180412039284N2**

Registration date: **2018-07-19, 1397/04/28**

Registration timing: **prospective**

Last update: **2018-07-19, 1397/04/28**

Update count: **0**

Registration date

2018-07-19, 1397/04/28

Registrant information

Name

Hedieh Rahmani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-22, 1397/06/31
Expected recruitment end date
2018-12-21, 1397/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effect of chitosan supplementation on changes of weight, glycemic risk factors, lipid profile, serum inflammatory factors, adipokines and total antioxidant capacity in patients with nonalcoholic fatty liver disease (NAFLD)

Public title

The effect of chitosan supplementation in patients with nonalcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Aged between 18-65 years (both genders) Diagnosis of nonalcoholic fatty liver disease by ultrasound Willingness to participate No allergies to seafood

Exclusion criteria:

Suffering from viral hepatitis, liver cirrhosis, Wilson's disease, acute fatty liver, hepatocellular carcinoma, hypothyroidism, lipodystrophy, diseases that involves bile ducts History of chronic liver disease History of significant weight loss (more than 10% of body weight during 6 months ago) or weight loss surgery History of antioxidant supplementation, omega 3 and milk thistle during 6 months ago History of liver damaging drugs History of cardiovascular History of renal disease Alcohol consumption more than 20 gram per day Pregnancy Lactation Menopause Energy consumption less than 800 or more than 4200 kilocalorie per day

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

First, a nonrandom sample is chosen among the individuals ,who has the inclusion criteria, using a simple sampling method. Then, the randomization is performed between study groups. One of the hospital nurses ,who

has not been blinded in the study, will change the names of chitosan and placebo on their packages to A and B (for example). Then, the researcher will distribute A and B packages among patients, who are referring to Golestan Hospital, using a randomized block method (ABAB, BABA, AABB, BBAA, ABBA, BAAB; A, first person; B, Second person; A, third person; B, fourth person B etc.). Finally, choosing the blocks will be continued until reaching the sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

Study participants, the main researcher, the specialist, the person who collects the data and analyzes the outcomes are blinded. Supplement and placebo are the same in shape and color, so study participants will not be aware of supplements' content. One of the nurses in hospital will change the names of chitosan and placebo on their packages to A and B, so the main researcher will not be aware of supplements' content that are given to the patients. The specialist, the person who collects the data (the main researcher) and analyzes the outcomes (the main researcher) will not be aware of supplements' content.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University Of Medical Sciences

Street address

Ahvaz Jundishapur University Of Medical Sciences, Golestan Ave, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Approval date

2018-05-12, 1397/02/22

Ethics committee reference number

IR.AJUMS.REC.1397.211

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Glycated hemoglobin A1c

Timepoint

Before the intervention and twelve weeks after

Method of measurement

Spectrophotometry

2

Description

Fasting blood glucose

Timepoint

Before the intervention and twelve weeks after

Method of measurement

Enzymatic method

3

Description

Plasma insulin

Timepoint

Before the intervention and twelve weeks after

Method of measurement

Calorimetry

4

Description

Serum adiponectin

Timepoint

Before the intervention and twelve weeks after

Method of measurement

ELISA

5

Description

Serum leptin

Timepoint

Before the intervention and twelve weeks after

Method of measurement

ELISA

6

Description

Interleukin-6

Timepoint

Before the intervention and twelve weeks after

Method of measurement

ELISA

7

Description

TNF-alpha

Timepoint

Before the intervention and twelve weeks after

Method of measurement

ELISA

8

Description

Serum total antioxidant capacity (TAC)

Timepoint

Before the intervention and twelve weeks after

Method of measurement

ELISA

9

Description

High Density Lipoprotein (HDL)

Timepoint

Before the intervention and twelve weeks after

Method of measurement

Enzymatic method

10

Description

Low Density Lipoprotein (LDL)

Timepoint

Before the intervention and twelve weeks after

Method of measurement

Enzymatic method

11

Description

Total cholesterol

Timepoint

Before the intervention and twelve weeks after

Method of measurement

Enzymatic method

12

Description

Triglyceride

Timepoint

Before the intervention and twelve weeks after

Method of measurement

Enzymatic method

Secondary outcomes

1

Description

weight

Timepoint

Before the intervention and twelve weeks after

Method of measurement

Scale (seca)

2

Description

Body Mass Index (BMI)

Timepoint

Before the intervention and twelve weeks after

Method of measurement

Weight (kg) divided to height square

3

Description

Visceral Adiposity Index

Timepoint

Before the intervention and twelve weeks after

Method of measurement

Formula based on these variables: BMI, waist circumference, HDL-C and triglyceride (TG)

4

Description

Aspartate aminotransferase (AST)

Timepoint

Before the intervention and twelve weeks after

Method of measurement

Enzymatic method

5

Description

Alanine aminotransferase (ALT)

Timepoint

Before the intervention and twelve weeks after

Method of measurement

Enzymatic method

6

Description

Model-insulin resistance index (HOMA-IR)

Timepoint

Before the intervention and twelve weeks after

Method of measurement

HOMA= fasting serum insulin (μ U/ml) \times fasting plasma glucose (mM/L)/22.5

7

Description

body fat percentage

Timepoint

Before the intervention and twelve weeks after

Method of measurement

Bioelectrical Impedance Analysis (BIA)

Intervention groups

1

Description

Intervention group: Consumption of chitosan (dose of supplements: 500 miligram) twice a day (one before

lunch and one before dinner) for 12 weeks. Chitosan supplements are provided by Karen company

Category

Treatment - Drugs

2

Description

Control group: Consumption of placebo (dose of placebo: 500 miligram) twice a day (one before lunch and one before dinner) for 12 weeks. Placebo is provided by Karen company

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital of Ahvaz

Full name of responsible person

Hedieh Rahmani

Street address

Golestan Hospital, Golestan Ave, Ahvaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Badavi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Hedieh Rahmani

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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

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Full name of responsible person

Dr. Bizhan Helli

Position

Assistant Professor

Latest degree

Specialist

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Student

Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available