

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Sep 2026

The effect of chitosan supplementation on changes of body weight, glycemic risk factors (fasting glucose, insulin, glycated hemoglobin), lipid profile and visceral adiposity index in patients with nonalcoholic fatty liver disease (NAFLD)

Protocol summary

Study aim

Evaluation of the effect of chitosan supplementation on body weight changes, glycemic risk factors, lipid profiles and visceral obesity index in patients with non-alcoholic fatty liver (NAFLD)

Design

A clinical trial with (placebo) control group, with parallel groups, triple blind, randomized

Settings and conduct

This is a clinical trial study performed on Fatty liver patients referred to Golestan Hospital in 1397, who has been diagnosed at least 6 months ago. The informed consent and other information are 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 (supplements and placebo).

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; BMI between 25 to 40 Exclusion criteria: Suffering from viral hepatitis, liver cirrhosis, Wilson's disease, acute fatty liver, hepatocellular carcinoma, hypothyroidism, lipodystrophy, diseases that involve 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 drug; history of cardiovascular and renal disease; 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

body weight; glycated hemoglobin; fasting blood glucose; insulin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180412039284N1**

Registration date: **2018-05-09, 1397/02/19**

Registration timing: **prospective**

Last update: **2018-05-09, 1397/02/19**

Update count: **0**

Registration date

2018-05-09, 1397/02/19

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

2018-06-21, 1397/03/31
Expected recruitment end date
 2018-10-21, 1397/07/29
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 The effect of chitosan supplementation on changes of body weight, glycemic risk factors (fasting glucose, insulin, glycated hemoglobin), lipid profile and visceral adiposity index in patients with nonalcoholic fatty liver disease (NAFLD)

Public title
 The effect of chitosan supplementation in patients with nonalcoholic fatty liver disease (NAFLD)

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Individuals of both genders (males and females) will be selected to participate in the study, aged between 18 and 65 years old that their fatty liver diagnosed by ultrasound testing No allergies to seafood
Exclusion criteria:
 Hepatitis, liver cirrhosis, Wilson's disease, acute fatty liver, pregnancy, hepatocellular carcinoma, hypothyroidism and chronic liver disease Lipodystrophy Menopause Parenteral nutrition Diseases that involve bile ducts and bile ducts Severe weight loss (more than 10% of body weight) during last 6 months and weight loss surgery Congenital metabolic diseases Consumption of Herbal Supplements in the last three months Taking drugs that cause fatty liver and liver toxicity (amiodarone, antivirals, spirin, non-steroidal anti-inflammatory drugs, corticosteroids, methotrexate, tamoxifen, tetracycline, valproic acid Pregnancy and lactation Consumption of Omega 3 and Vitamin E and other antioxidant supplements over the past 6 months History of cardiovascular disease and kidney disease BMI between 25 and 40 Unwillingness to participate Energy consumption less than 800 or more than 4200kcal/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, individuals who have the characteristics necessary to enter the study are usually taken from a non-random sample using a simple sampling method. Then, randomization is done between study groups. In this study, a block randomization method (including 4 locks) is used. One of the study partners who has not been blindfolded, named chitosan and placebo with the letters A and B (for example). Then, the researcher distributed A and B packages among patients referring to Golestan Hospital in a randomized block method (ABAB, BABA, AABB, BBAA, ABBA, BAAB; A, first person; B, Second person; A, third person; B, fourth person B etc.). Then, selecting the blocks are continued until reaching the sample size.

Blinding (investigator's opinion)
 Triple blinded

Blinding description
 One of the study partners who has not been blindfolded, named chitosan and placebo with the letters A and B (for example). Then, the researcher distributed A and B packages among patients referring to Golestan Hospital in a randomized block method (ABAB, BABA, AABB, BBAA, ABBA, BAAB; A, first person; B, Second person; A, third person; B, fourth person B etc.).

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, Ahvaz, Khuzestan, Iran
City
 Ahvaz
Province
 Khuzestan
Postal code
 61357-15794

Approval date
 2018-03-02, 1396/12/11

Ethics committee reference number
 IR.AJUMS.REC.1396.1045

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver
ICD-10 code
K76.0
ICD-10 code description
Nonalcoholic fatty liver disease [NAFLD]

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
LDL
Timepoint
Before the intervention and twelve weeks after
Method of measurement
enzymatic method

5

Description
HDL
Timepoint
Before the intervention and twelve weeks after
Method of measurement
enzymatic method

6

Description
total cholesterol
Timepoint
Before the intervention and twelve weeks after
Method of measurement
enzymatic method

7

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 12 weeks after
Method of measurement
scale (seca)

2

Description
BMI
Timepoint
before the intervention and 12 weeks after
Method of measurement
weight (kg) divided to height square

3

Description
visceral adiposity index
Timepoint
before the intervention and 12 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 12 weeks after
Method of measurement
enzymatic method

5

Description
alanine aminotransferase (ALT)
Timepoint
before the intervention and 12 weeks after
Method of measurement
enzymatic method

6

Description
model-insulin resistance index (HOMA-IR)
Timepoint
before the intervention and 12 weeks after

Method of measurement

HOMA= fasting serum insulin (μU/ml)× fasting plasma glucose (mM/L)/22.5

7

Description

body fat percentage

Timepoint

before the intervention and 12 weeks after

Method of measurement

BIA

Intervention groups

1

Description

Intervention group: 1000 miligram of chitosan supplement (chitosan dose:500 miligram; twice a day)

Category

Lifestyle

2

Description

control group: 1000 miligram placebo

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital of Ahvaz

Full name of responsible person

Hedieh Rahmani

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Sponsors / Funding sources

1

Sponsor

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Full name of responsible person

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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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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

Yes - There is a plan to make this available

Clinical Study Report

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

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

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments

-