Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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 inform 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 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 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)

Phone
+98 61 3373 8317

Email address
rahmani.he@ajums.ac.ir

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

Khouzestan

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 mehod

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
Street address
Ahvaz jundishapur university of medical sciences, Golestan Hospital, Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Email
rahmani.he@ajums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Badavi
Street address
Jundishapur university of medical sciences, Golestan Ave, Ahvaz, Khuzestan, Iran
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3373 8317
Email
rahmani.he@ajums.ac.ir
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
Street address
Ahvaz Jundishapur university of medical sciences, Golestan Ave, Ahvaz, Khuzestan
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Phone
+98 61 3373 8317
Email
rahmani.he@ajums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person
Dr. Bizhan Helli

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Nutrition

Street address
Ahvaz Jundishapur university of medical sciences, Golestan Ave, Ahvaz, Khuzestan

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Phone
+98 61 3373 8317

Email
bizahnhelli@yahoo.com

Person responsible for updating data

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

Street address
Ahvaz Jundishapur university of medical sciences, Golestan Ave

City
Ahvaz

Province
Khouzestan

Postal code
61357-15794

Phone
+98 61 3373 8317

Email
rahmani.he@ajums.ac.ir

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
-