Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 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 inform 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

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Iran (Islamic Republic of)

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+98 61 3373 8317

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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 (μU/ml)× 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
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
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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