Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jul 2026

Investigating the effect of chitosan supplementation on non-alcoholic fatty liver steatosis patients

Protocol summary

Study aim
Determining the effect of chitosan supplementation on steatosis in patients with non-alcoholic fatty liver disease

Design
Clinical trial with control group, double blind, randomized, phase 3 on 60 patients. Sealed and waxed opaque envelopes were used for randomization.

Settings and conduct
In all clinics covered by Mashhad University of Medical Sciences, posters and information related to the project will be posted. People interested in the plan are selected after visiting the gastroenterology clinic and an initial examination by a gastroenterology and fatty liver specialist, and are referred to the radiology clinic, and after the definitive diagnosis of fatty liver, they are referred to the nutrition clinic. The plan is explained to the people who have the necessary conditions and criteria to enter the study, and after obtaining written consent, they are selected and entered the study.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Age 18 to 65 years; Fatty liver grade 1 and 2; Absence of morbid obesity; Lack of breastfeeding and pregnancy; No alcohol consumption; lack of immunity; Absence of liver and kidney failure; not taking hepatotoxic drugs; No allergy to marine products; No bariatric surgery Exclusion criteria: pregnancy and breastfeeding; morbid obesity; alcohol consumption; suffering from autoimmune disorders; liver or kidney failure; use of hepatotoxic drugs; History of allergy to seafood

Intervention groups
Intervention group: They will receive six chitosan supplements every day for 60 days (2 months). Control group: They will receive six placebo capsules every day for 60 days (2 months).

Main outcome variables
Severity of hepatic steatosis; body fat percentage; amount of physical activity; the amount of energy intake; the amount of body mass; waist size

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230522058260N1**
Registration date: **2025-03-08, 1403/12/18**
Registration timing: **prospective**

Last update: **2025-03-08, 1403/12/18**
Update count: **0**

Registration date
2025-03-08, 1403/12/18

Registrant information

Name
Mahsa Roueeni

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-09, 1404/01/20

Expected recruitment end date
2025-10-22, 1404/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Investigating the effect of chitosan supplementation on non-alcoholic fatty liver steatosis patients

Public title

Investigating the effect of chitosan supplementation on non-alcoholic fatty liver steatosis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 65 years Diagnosis of fatty liver grade one and two Filling the informed consent form by the individual Not during pregnancy and breastfeeding. Do not have morbid obesity (body mass index greater than 40 Do not have a history of consuming more than 20 grams of alcohol per day for women and more than 30 grams per day for men. Suffering from any type of immune disorder including: autoimmune disorders, cancer, human immunodeficiency virus (HIV) Do not suffer from liver or kidney failure, other liver diseases such as hepatitis, alcoholic fatty liver. Do not use hepatotoxic drugs such as sodium valproate. Do not have a history of food allergy to marine products and herbal supplements or chitosan. Do not have a history of bariatric surgery to lose weight

Exclusion criteria:

Pregnancy and breastfeeding Morbid obesity (body mass index greater than 40) History of alcohol consumption (more than 20 grams per day for women and more than 30 grams per day for men), Having any type of immune disorder, including: autoimmune disorders, cancer, human immunodeficiency virus (HIV) Suffering from liver or kidney failure, other liver diseases such as hepatitis, alcoholic fatty liver Taking hepatotoxic drugs such as sodium valporate History of food allergy to chitosan and herbal supplements History of bariatric surgery for weight loss Hypothyroidism, diabetes, high blood pressure, diet, medications and weight loss supplements

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Allocation concealment Allocation concealment is a technique to ensure that the random allocation process is truly random and unbiased. RCTs use allocation concealment to decide which patients will receive the real drug and which will receive a placebo. In this study, the researcher wants all study groups to have equal sample size, so she uses limited randomization of the block randomization type. in such a way that: We name two treatment methods (intervention and placebo) with letters A and B. We consider each block as four. For a sample size of 60 people, 15 blocks of 4 are needed. For blocks of 4, there will be the following six different states (permutations), similar to the order below: AABB(1) -ABAB(2)- ABBA(3) -BBAA(4) -BABA(5) -BAAB(6) With the help of Randomaize.com software, we choose random numbers between 1 and 6. 15 We write down the combination corresponding to the numbers: 6 2 5 4 3 5 5 6 5 1 3 2 5 5 3 Then, when each participant enters the study, they will be treated according to the order of the letter (A or B). Use of sealed opaque envelopes with random sequence:(Sequentially numbered, sealed opaque envelopes) This method is one of the common methods of hiding random allocation, which is abbreviated as the method SNOSE. In this method, first a random sequence is created by one of the mentioned methods, then based on the sample size of the research, a number of letter envelopes with aluminum wrappers (in order to make the contents of the envelopes unclear) are prepared and each of the generated random sequences is recorded on a card and the cards are placed inside the letter envelopes in order. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order.Finally, the lid of the letter envelopes is glued and placed in a box. At the time of registration of the participants, based on the order in which the eligible participants entered the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding is used to reduce the amount of error in clinical trial studies where the researcher or the group of researchers do not consciously or unconsciously cause errors in the study, for example, it is possible to consciously or unconsciously measure the outcome in the intervention group and the control group with different sensitivity and precision, or in encouraging and following up the patient to comply with the treatment in two groups, they may deal with two different methods. Due to the use of a placebo similar to the interventional treatment, the doctor related to the participants and the participants will not be informed of the treatment assigned, and the analyst will also be unaware of the treatment assigned to the two groups. Finally, after analyzing the data, the researcher who prepared the packages reveals the code A and B. Except for the pharmacist, none of the participants and researchers and analysts will know about the drug or placebo until the end of the study. In this way, the groups are identified only with the code A and B. The drugs are prepared in the same packaging and in the same form and are packaged by a person in the pharmaceutical company who is outside the research, in the form of coded packages A and B. The password of the codes is kept securely in the system so that the codes can be opened after collecting the data.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Lorestan University of Medical Sciences

Street address
University Blvd، Khorramabad، Lorestan

City
Khorramabad

Province
Lorestan

Postal code
6819789741

Approval date
2024-11-26, 1403/09/06

Ethics committee reference number
IR.LUMS.REC.1403.341

Health conditions studied

1

Description of health condition studied
Fatty liver

ICD-10 code
K76.0

ICD-10 code description
Nonalcoholic fatty liver disease [NAFLD]،Central haemorrhagic necrosis of liver،Infarction of liver،Hepatorenal syndrome،Chronic passive congestion of liver

Primary outcomes

1

Description
The amount of hepatic steatosis at the beginning and end of the study is measured by elastography as the primary outcome.

Timepoint
The beginning and end of the study

Method of measurement
It is measured by elastography.

Secondary outcomes

1

Description
Status of receiving food

Timepoint
At the beginning, during the study and at the end of the study, it is measured and checked

Method of measurement
Remembered 3 days of food

Intervention groups

1

Description
Intervention group: People in this group receive capsules containing chitosan, with a dose of 500 mg, 6 pieces per day, 2 pieces half an hour before each main meal (breakfast, lunch, dinner), for 60 days (2 months), along with dietary recommendations according to the grade of the disease. It is recommended that people consume each chitosan capsule with 1 glass of water.

Category
Treatment - Other

2

Description
Control group: People in this group receive capsules containing 500 mg of Avicel, six capsules per day, half an hour before each main meal (breakfast, lunch, dinner), for 60 days (2 months), along with dietary recommendations according to the grade of the disease. It is recommended that people take each placebo capsule with 1 glass of water.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital Clinic mashhad

Full name of responsible person
Dr. Ebrahim Fallahi

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On the edge of Imam Reza Square (AS)، Ibn Sina St، Mashhad

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Khoram-Abad 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
Khoram-Abad University of Medical Sciences
Full name of responsible person
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Position
Professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD

Protecting patients' privacy

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

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