Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Chitosan Functional Fiber on Metabolic Indicators and Hepatic Steatosis Predictors in Individuals with Non-alcoholic Fatty Liver Disease

Protocol summary

Study aim

Determining the effect of chitosan functional fiber on metabolic indicators and hepatic steatosis predictors in individuals with NAFLD.

Design

This study is a phase 3 double-blind, randomized, controlled clinical trial with two parallel groups (intervention and control). 36 eligible individuals will be randomly assigned to each group by means of the block randomization method (72 participants in total).

Settings and conduct

72 eligible individuals referred to Moslemin hospital (Shiraz), after signing an informed consent form, were randomly assigned to 2 study groups. Along with the low-calorie diet, the participants received chitosan supplements or a placebo, named the same as the groups' names (A and B) for blinding the participant and the research team, with water daily for 8 weeks, daily. Anthropometrics, liver enzymes, fasting blood sugar, lipid profile, liver steatosis indicators, dietary intake, and physical activity will be assessed before and after the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: adult (>18 years old) with grade 1 to 3 of NAFLD, with no history of shellfish or shrimp allergy, alcohol abuse (more than 10 grams for women and 20 grams for men per day), viral hepatitis, liver cancer or other cancers, diabetes, untreated thyroid problems, mental or kidney disorders, and nutritional supplements consumption in the 3 months before the study, pregnancy or breastfeeding at the initiation of the study; Exclusion conditions: drinking alcohol, beginning pregnancy, taking fiber containing supplements, and showing signs of allergy to supplements،

Intervention groups

The participants will consume chitosan capsules (1.5 gr, Karen Co., Iran) in the intervention group or placebo (control group) for 8 weeks, daily. Also, all the participants will be given a low-calorie diet (with a reduction of 500 kcal).

Main outcome variables

Aspartate transaminase

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140502017522N4**
Registration date: **2023-03-23, 1402/01/03**
Registration timing: **prospective**

Last update: **2023-03-23, 1402/01/03**
Update count: **0**

Registration date

2023-03-23, 1402/01/03

Registrant information

Name

Maryam Taghdir

Name of organization / entity

Baqiyatallah University of medical sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2023-10-22, 1402/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Chitosan Functional Fiber on Metabolic Indicators and Hepatic Steatosis Predictors in Individuals with Non-alcoholic Fatty Liver Disease

Public title

The Effect of Chitosan in the management of non-alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adults (aged over 18 years old) with grade 1 to 3 non-alcoholic fatty liver disease Not abusing alcohol (more than 10 grams for women and 20 grams for men per day) Not having viral hepatitis, liver cancer, or other cancers Not suffering from diabetes or untreated thyroid problems Not suffering from mental disorders No history of kidney disease Willingness to cooperate

Exclusion criteria:

Taking nutritional supplements and fiber containing supplements in the 3 months before the study History of allergy to chitosan supplements, shellfish or shrimp Pregnancy Being in breastfeeding period

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation will be done using the block randomization method (blocks of two with a 1:1 ratio). In this way, before conducting the study, blocks of two will be prepared by a person familiar with the block randomization method. Then one of the blocks is selected to determine the group assigned to the first two participants, and the second block should be assigned to the third and fourth participants. Selecting blocks will be done using a coin toss. This method will be used to randomly determine the allocation group of participants until the end of the desired sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the groups' names will be replaced by the letters A and B by the person who made the random allocation sequence, and the allocated group for each participant will be placed in sealed opaque envelopes. The envelopes are numbered according to the sequence and the envelopes will not be opened until the initiation of the study. In this way, the research team including researchers, clinical evaluators, statisticians, and participants will be blinded to the assigned group. Also, the supplement and placebo will be the same in terms of shape, color, and smell, and will be placed in packages with a similar appearance. Chitosan and placebo packages are also named by the same person, with the same letters as groups (A or B). In this way, the participant and the research team will be blinded with regard to receiving the supplement or placebo.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatallah Hospital

Street address

Baqiatallah University, South Sheikh Baha'i st., Molasadra st., Vanak sq.,

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2023-02-06, 1401/11/17

Ethics committee reference number

IR.BMSU.BAQ.REC.1401.112

Health conditions studied

1

Description of health condition studied

Non-alcoholic Fatty Liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Aspartate aminotransferase (AST)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Enzyme-linked immuno_sorbent assay (ELISA)

Secondary outcomes

1

Description
Weight
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Scale

2

Description
Waist circumference
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Tape measure

3

Description
Body mass index (BMI)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Standard formula

4

Description
Fasting blood sugar (FBS)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Standard enzymatic method

5

Description
Total cholesterol
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Standard enzymatic method

6

Description
High density lipoprotein (HDL)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Standard enzymatic method

7

Description
Low density lipoprotein (LDL)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Standard enzymatic method

8

Description
Triglycerides (TG)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Standard enzymatic method

9

Description
Gamma-glutamyl transferase (GGT)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Enzyme-linked immuno_sorbent assay (ELISA)

10

Description
Fatty liver index (FLI)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Standard formula

11

Description
Hepatic steatosis index (HSI)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Standard formula

12

Description
Triglyceride-glucose index (TyG)

Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Standard formula

13

Description
Alanine transaminase (ALT)
Timepoint
At the beginning of the study (before the intervention) and the end of the study (8 weeks after the intervention)
Method of measurement
Enzyme-linked immuno_sorbent assay (ELISA)

Intervention groups

1

Description
Intervention group: Daily intake of 1.5 grams of chitosan functional powder (Karen Co., Iran) for 8 weeks in the form of capsules along with a low-calorie diet (500 kcal reduction)
Category
Treatment - Other

2

Description
Control group: Daily intake of placebo (Karen Co., Iran) for 8 weeks in the form of capsules along with a low-calorie diet (500 kcal reduction)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Moslemin Hospital
Full name of responsible person
Mohammad Ali Mohsenpour
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Maryam Taghdir
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
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Person responsible for updating data

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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
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