Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Evaluation of the effects of Chia seeds (Salvia hispanica) on nutritional status, metabolic factors, liver function, inflammatory hematologic and atherogenic indices in obese patients with non-alcoholic fatty liver disease

Protocol summary

Study aim

To determine the effects of Chia seeds on nutritional status, metabolic factors, liver function, inflammatory hematologic and atherogenic indices in obese patients with non-alcoholic fatty liver disease

Design

A single-blind, controlled, randomized clinical trial using random assignment software (RAS) and randomized block method on 38 patients.

Settings and conduct

Study location: Tabriz University of Medical Sciences Nutrition Science Research Center; Study population: patients with non-alcoholic fatty liver disease; blinding: single-blind, in this study, the person who analyzes is blinded; A research assistant not otherwise involved in the study, will randomly allocate the participants into one of the two experimental groups (1:1), using the Random allocation software (RAS) and randomized block procedure. The person (completely unrelated to the study) who will prepare the supplement sachets will assigne a 3-digit code for each treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: both genders; age 18 to 60 years; body mass index 30- 39.9 Kg/m; hepatic steatosis; willing to participate in the study. Exclusion criteria: athletes; pregnancy; breastfeeding and menopause; following a special diet; taking medications for weight-reducing or any other medications affecting liver function for 3 months before or during the study; suffering from certain diseases

Intervention groups

The intervention group will receive two- 20 gr sachets of chia seeds per day along with weight loss diet while the control group will only receive weight loss diet

Main outcome variables

Nutritional status (intake of energy and macronutrients, appetite status); Anthropometric indices and body composition; Metabolic factors; Liver function and liver fibrosis score; Hematological indicators of inflammation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100209003320N23**
Registration date: **2024-01-30, 1402/11/10**
Registration timing: **prospective**

Last update: **2024-01-30, 1402/11/10**
Update count: **0**

Registration date

2024-01-30, 1402/11/10

Registrant information

Name

Mehrangiz Ebrahimi mamagani

Name of organization / entity

Health & Nutrition faculty of Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date
2024-07-22, 1403/05/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effects of Chia seeds (Salvia hispanica) on nutritional status, metabolic factors, liver function, inflammatory hematologic and atherogenic indices in obese patients with non-alcoholic fatty liver disease

Public title
The effect of chia seeds on non-alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Both genders Age range of 18 to 60 years body mass index= 30- 39.9 Kg/m2 Hepatic steatosis based on ultrasound findings (grade 1 and 2) willingness to participate in the study
Exclusion criteria:
Athletes pregnancy breastfeeding menopause Under infertility treatment taking birth control pills estrogen therapy Smoking history of alcohol consumption Taking medications including chemical or herbal medications for weight loss anti-hypertensive Fat-lowering drugs Sugar-lowering drugs any nutritional supplements from 3 months before the study Having cardiovascular diseases Liver dysfunction Kidney dysfunction Intestinal dysfunction Thyroid dysfunction Parathyroid dysfunction known autoimmune diseases polycystic ovary syndrome cancers Following a special diet in the last three months performing weight loss surgery in the last one year Taking Phenytoin medicine Taking amoxifene medicine Taking lithium medicine Performing or being a candidate for liver transplantation
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **38**
Randomization (investigator's opinion)
Randomized
Randomization description
A research assistant not otherwise involved in the study, will randomly allocate 38 patients into one of the two experimental groups (1:1), using the Random allocation software (RAS) and randomized block procedure (age (18-39 vs 39-60 years)- gender (female vs male) and BMI (<35 kg/m2 vs. ≥35 kg/m2)).
Blinding (investigator's opinion)
Single blinded
Blinding description
A research assistant not otherwise involved in the study, randomly allocated the participants into one of the two experimental groups (1:1), using the Random allocation software (RAS) and randomized block procedure. The person (completely unrelated to the study) who will prepare the supplement sachets will assigne a 3-digit code for each treatment.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences, Attar Neishaburi St, Golgasht St.
City
Tabriz
Province
East Azarbaijan
Postal code
5166614711
Approval date
2024-01-01, 1402/10/11
Ethics committee reference number
IR.TBZMED.REC.1402.751

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver disease
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Insulin
Timepoint
Baseline and after 8 weeks

Method of measurement
ELISA method

2

Description
Hemoglobin A1C
Timepoint
Baseline and after 8 weeks
Method of measurement
chromatography

3

Description
total cholesterol
Timepoint
Baseline and after 8 weeks
Method of measurement
Enzymatic method

4

Description
Triglyceride
Timepoint
Baseline and after 8 weeks
Method of measurement
Enzymatic method

5

Description
HDL cholesterol
Timepoint
Baseline and after 8 weeks
Method of measurement
Enzymatic-colorimetric method using spectrophotometer

6

Description
LDL cholesterol
Timepoint
Baseline and after 8 weeks
Method of measurement
Based on the Friedelwald formula

7

Description
Insulin resistance indices (HOMA-IR, HOMA-B and QUICKI)
Timepoint
Baseline and after 8 weeks
Method of measurement
Based on the formula

8

Description
Body mass index(BMI)
Timepoint
Baseline and after 8 weeks
Method of measurement
Based on the formula

9

Description
Waist circumference
Timepoint
Baseline and after 8 weeks
Method of measurement
tape measure

10

Description
Waist to hips ratio (WHR)
Timepoint
Baseline and after 8 weeks
Method of measurement
Based on the formula

11

Description
Waist to Height ratio (WHTR)
Timepoint
Baseline and after 8 weeks
Method of measurement
Based on the formula

12

Description
Fat mass
Timepoint
Baseline and after 8 weeks
Method of measurement
Body analyzer

13

Description
Fat Free mass
Timepoint
Baseline and after 8 weeks
Method of measurement
Body analyzer

14

Description
Energy, macronutrients and micronutrients intake
Timepoint
Baseline and after 8 weeks
Method of measurement
24- hr food recall questionnaire for 3 days and Nutritionist 4 software

15

Description
Physical activity level
Timepoint
Baseline and after 8 weeks
Method of measurement

IPAQ Questionnaire- short form

16

Description
Appetite status
Timepoint
Baseline and after 8 weeks
Method of measurement
Validated appetite questionnaire

17

Description
Body weight
Timepoint
Baseline and after 8 weeks
Method of measurement
Scale

18

Description
Fasting glucose
Timepoint
Baseline and after 8 weeks
Method of measurement
Enzymatic method

19

Description
Complete blood cell count (CBC)
Timepoint
Baseline and after 8 weeks
Method of measurement
Coulter counter

20

Description
Serum Albumin
Timepoint
Baseline and after 8 weeks
Method of measurement
using BROMOCRESOL GREEN

21

Description
Platelets count
Timepoint
Baseline and after 8 weeks
Method of measurement
Coulter counter

22

Description
Liver fibrosis score
Timepoint
Baseline and after 8 weeks
Method of measurement
based on formula

23

Description
total body water
Timepoint
Baseline and after 8 weeks
Method of measurement
Using bioelectric impedance analyzer

24

Description
Hematological indicators of inflammation (the number of monocytes, neutrophils, lymphocytes and platelets in whole blood and the estimation of the ratios of monocytes, neutrophils and platelets to lymphocytes)
Timepoint
Baseline and after 8 weeks
Method of measurement
Coulter counter

25

Description
Atherogenic indices (LDL-C/HDL-C, TC/HLD-C, TG/HDL-C, nonHDL-C/HDL-C)
Timepoint
Baseline and after 8 weeks
Method of measurement
Based on the formula

26

Description
Hip circumference
Timepoint
Baseline and after 8 weeks
Method of measurement
tape measure

27

Description
Serum ferritin
Timepoint
Baseline and after 8 weeks
Method of measurement
Electrochemiluminescence method

Secondary outcomes

1

Description
Fatty liver grade
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Ultrasonigraphy findings

2

Description

Alanine aminotransferase (ALT)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Enzymatic method

3

Description

Aspartate aminotransferase (AST)

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Enzymatic method

Intervention groups

1

Description

"Intervention group": patients in this group will receive chia seeds along with a weight loss diet, taking into account that 100 grams of chia seeds contain 486 calories (approximately 200 calories for 40 grams of chia seeds per day) to moderate the amount of weight loss Calories in the intervention group will be reduced by 700 kilocalories and to adjust the diet with the distribution of macronutrients as 55% carbohydrates, 30% fat, 15% protein. Daily, two 20-gram sachets of Paraguayan chia seeds will be purchased from Isfahan Herbal Company in sachet form. 20 grams will be packed, half an hour before two meals a day, and they will be consumed in a glass of lukewarm water. The duration of the study will be 8 weeks. People in the intervention group will be asked to bring unused sachets with them every two weeks to determine compliance. Weight control and distribution of sachets will be done every two weeks

Category

Treatment - Drugs

2

Description

"Control group": patients in this group will only receive a weight loss diet (500 kcal reduction) along with a glass of water before two main meals for 8 weeks.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz University of Medical Science

Full name of responsible person

Dr.Mehrangiz Ebrahimi- Mameghani

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mehrangiz Ebrahimi- Mameghani

Position

professor

Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data collected for the primary outcomes will be shared
When the data will become available and for how long
The access period starts 12 months after the results are published
To whom data/document is available
The data will be available only to people working in scientific institutions
Under which criteria data/document could be used
The data of this study will be available to other researchers only for meta-analysis studies
From where data/document is obtainable
Maryam Parimi, email address: maryam.parimi6@gmail.com, phone number: 09109337321
What processes are involved for a request to access data/document
The applicant should provide a brief explanation of the goals and methodology of his meta-analysis. The applicant's request will be reviewed and if approved, the data will be sent to the applicant via email. All these steps will not take more than 15 days
Comments