Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Sep 2026

Evaluating the effect of black garlic on liver steatosis and enzymes, lipid profile, insulin resistance, and anthropometric measurements in patients with non-alcoholic fatty liver disease

Protocol summary

Study aim
Determining the effect of black garlic on liver steatosis and enzymes, lipid profile, insulin resistance, and anthropometric measurements in patients with non-alcoholic fatty liver disease

Design
Parallel randomized controlled trial

Settings and conduct
The present study aiming to evaluate effect of black garlic on liver steatosis and enzymes, lipid profile, insulin resistance, and anthropometric measurements in patients with non-alcoholic fatty liver disease. This study will take place in Imam Khomeini Hospital in Urmia and it is a parallel randomized controlled clinical trial. 110 patients will be randomly assigned to 2 groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with non-alcoholic fatty liver disease more than 18 years from both sexes Patients with non-alcoholic fatty liver disease with a BMI less than 30; patients with non-alcoholic fatty liver disease diagnosed through ultrasound and referred to Imam Hospital Gastroenterology Clinic. Exclusion criteria: Special diets; pregnancy or lactation during the study; viral hepatitis; alcohol consumption or history of alcohol consumption; non-compliance to our recommendations regarding Black garlic consumption; untreated hypothyroidism; renal diseases; taking drugs that increase liver enzymes; alpha antitrypsin deficiency; gastrointestinal disease such as celiac disease; menopause; diabetes mellitus; herbal therapy; heart failure and bone disease.

Intervention groups
In the intervention group, in addition to the usual treatment, will be recommended to consume 6 grams of black garlic in total per day before morning and evening meal. In addition to the usual fatty liver treatment, the control group was advised to follow FAO (Food and Agriculture Organization) recommendations by the researcher.

Main outcome variables
Liver steatosis; Insulin resistance; Liver enzyme; Lipid profile; Anthropometric measurements

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201204049599N6**
Registration date: **2022-10-26, 1401/08/04**
Registration timing: **prospective**

Last update: **2022-10-26, 1401/08/04**
Update count: **0**

Registration date
2022-10-26, 1401/08/04

Registrant information

Name
Mohammad Reza Pashaee

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
2022-11-05, 1401/08/14

Expected recruitment end date
2023-03-16, 1401/12/25

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effect of black garlic on liver steatosis and enzymes, lipid profile, insulin resistance, and anthropometric measurements in patients with non-alcoholic fatty liver disease

Public title
Effect of Black garlic consumption on treatment of non-alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age older than 18 years old from both sexes BMI more than 30 Patients with non-alcoholic fatty liver disease diagnosed through ultrasound and referred to Imam Hospital Gastroenterology Clinic
Exclusion criteria:
Special diets Pregnancy and lactation during the study Viral hepatitis Alcohol consumption or history of alcohol consumption Non-compliance to our recommendations regarding Black garlic consumption Untreated hypothyroidism Renal diseases Taking drugs that increase liver enzymes Alpha antitrypsin deficiency Gastrointestinal disease such as celiac disease Menopause Diabetes mellitus Herbal therapy Heart failure and bone disease
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **56**
Randomization (investigator's opinion)
Randomized
Randomization description
The method used for randomization is Stratified Randomization. In this method, to eliminate the heterogeneity in age, gender and severity of steatosis variables, before applying random allocation, the samples will be classified based on these variables and then they will be randomly allocated into intervention and control groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Urmia University of Medical Sciences - Imam Khomeini University Hospita
Street address
Imam Khomeini Hospital; Ershad Blvd., Urmia, Iran
City
Urmia
Province
West Azarbaijan
Postal code
5715789397
Approval date
2022-08-30, 1401/06/08
Ethics committee reference number
IR.UMSU.HIMAM.REC.1401.041

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
Weight
Timepoint
At weeks 0, 12
Method of measurement
Scale, kg

2

Description
Body mass index
Timepoint
At weeks 0, 12
Method of measurement
Weight(kg)/[height(m)]2 , kg/m2

3

Description
Gamma Glutamyl transferase
Timepoint
At weeks 0,12

Method of measurement
Enzymatic method , IU/ Lit

4

Description
Alkalin Phosphatase
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method , IU/ Lit

5

Description
Aspartat transaminase
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method, IU/Lit

6

Description
Alanine Aminotransferase
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method, IU/ Lit

7

Description
Fasting blood sugar
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method, IU/ Lit

8

Description
Serum insulin
Timepoint
At weeks 0, 12
Method of measurement
Radioimmunoassay

9

Description
Waist circumference
Timepoint
At weeks 0, 12
Method of measurement
Cm

10

Description
Hepatic steatosis
Timepoint
Before intervention and three month after intervention
Method of measurement
Ultrasonography

11

Description
HDL cholesterol
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method, mg/dl

12

Description
Triglyceride
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method, mg/dl

13

Description
LDL cholesterol
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method, mg/dl

14

Description
Total cholesterol
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method, mg/dl

15

Description
HOMA-IR
Timepoint
At weeks 0, 12
Method of measurement
Formula

16

Description
Height
Timepoint
Before intervention
Method of measurement
Stadiometer, mm

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the intervention group, in addition to the usual treatment, will be recommended to consume 6 grams of black garlic in total per day before morning and evening meal for three months.
Category
Treatment - Other

2

Description
Control group: In addition to the usual fatty liver treatment, the control group was advised to follow FAO (Food and Agriculture Organization) recommendations by the researcher for three months.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Teaching Hospital, Urmia
Full name of responsible person
Mohammad Reza Pashaei
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr Saber gholizadeh
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Urmia University of Medical Sciences; Resalat Blvd., Urmia, Iran
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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
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Mohammad Reza Pashaei
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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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