Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of black garlic and garlic supplementation on cardiometabolic risk factors and fibroscan findings in patients with non-alcoholic fatty liver disease: a double-blind randomized controlled clinical trial

Protocol summary

Study aim
Determining the effect of garlic and black garlic supplementation on cardiometabolic and fibroscan indices in patients with nonalcoholic fatty liver disease

Design
After selecting the study subjects, the subjects will be divided into three groups: garlic, black garlic, and placebo (23 subjects in each group) in a 1:1 ratio using the block method. The blocks of six were created by the Random Allocation Software (RAS) statistical software and will be identified with the letters A, B, and C.

Settings and conduct
Patients in the intervention and placebo groups will receive 4 black garlic tablets each containing 500 mg of black garlic powder, 4 garlic tablets containing 500 mg of garlic powder, and 4 identical placebo tablets (two after breakfast and two after dinner) daily, respectively, along with dietary and physical activity recommendations. The capsules will be placed in containers and labeled by a third party in randomized blocks. Participants and care providers will be blinded to the intervention. Each patient will be assigned a code and will receive the capsules in the corresponding pre-packaged bottle.

Participants/Inclusion and exclusion criteria
Willingness to participate in the study Age 20-65 years Body mass index (BMI) 25 and above- Grade 1 to 3 hepatic steatosis diagnosed by ultrasound

Intervention groups
Patients in the intervention and placebo groups will receive 4 black garlic and garlic and placebo tablets daily along with dietary and physical activity recommendations. The capsules will be placed in containers and labeled by a third party based on random blocks. Participants and care providers will be blinded to the intervention.

Main outcome variables
Studying the effect of garlic and black garlic supplementation on cardiometabolic and fibroscan indices in patients with nonalcoholic fatty liver disease

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250608066122N1**
Registration date: **2025-06-27, 1404/04/06**
Registration timing: **prospective**

Last update: **2025-06-27, 1404/04/06**
Update count: **0**

Registration date
2025-06-27, 1404/04/06

Registrant information

Name
Soror Fathi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 913 547 1651

Email address
soroor.s1705@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-07-23, 1404/05/01

Expected recruitment end date
2025-11-22, 1404/09/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of black garlic and garlic supplementation on cardiometabolic risk factors and fibroscan findings in patients with non-alcoholic fatty liver disease: a double-blind randomized controlled clinical trial

Public title

Effect of black garlic on patients with non-alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Performance to participate in the study Age 20-65 years Body mass index (BMI) 25 and above Performed by ultrasound method

Exclusion criteria:

Pregnancy and breastfeedingSmokingIntake of large amounts of garlic in daily food intakeTreatment of heart, lung, kidney diseases, hepatitis, cirrhosis, biliary and immune system disorders, high blood pressure, hypothyroidism, Cushing's syndromeUse of drugs for consumption and blood sugar, vitamins E and D, ursodeoxycholic acid, phenytoin, tamoxifen, lithium, corticosteroids and methotrexateWeight loss and bariatric surgery in the last yearGarlic reviewNo use of other herbal supplements in the last three months

Age

From **20 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the study subjects, the subjects will be divided into three groups: garlic, black garlic, and placebo (n = 1 in each group) in a 1:1 ratio using the block method. The blocks of six were created by the statistical software Random Allocation Software (RAS) and will be identified with the letters A, B, and C.

Blinding (investigator's opinion)

Double blinded

Blinding description

Since participants do not know which group they are in, their beliefs about the treatment do not affect the outcome, and since clinical caregivers do not know which group is actually receiving treatment, they are unable to influence the course of treatment by revealing small clues.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of ahvaz University of Medical Sciences

Street address

No. 18, 2Ave., beheshti Blvd., shahin shahr Town

City

Isfahan

Province

Isfehan

Postal code

8314895182

Approval date

1994-10-26, 1373/08/04

Ethics committee reference number

IR.AJUMS.REC.1404.164

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

Monitoring people with fatty liver disease

Timepoint

'···At the beginning of the study (before starting work) and 12 weeks later

Method of measurement

Fibroscan

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:black garlic
Category
Treatment - Other

2

Description
Intervention group: garlic
Category
Treatment - Other

3

Description
Control group: placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Milad hospital
Full name of responsible person
Soroor fathi
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No. 18, 2 Ave., beheshti Blvd.,shahin shahr Town
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Soroor fathi
Proportion provided by this source
70
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
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Position
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Person responsible for updating data

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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
Patient information is private and cannot be published to protect the information.
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