

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 Pashae

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3198 8001

##### Email address

pashae.m@umsu.ac.ir

##### 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)]<sup>2</sup> , kg/m<sup>2</sup>

**3****Description**

Gamma Glutamyl transferase

**Timepoint**

At weeks 0,12

**Method of measurement**  
Enzymatic method , IU/ Lit

#### 4

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

#### 5

**Description**  
Aspartate 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 months 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

##### Street address

Imam Khomeini Hospital; Ershad Blvd., Urmia, Iran

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5715781351

##### Phone

+98 44 3346 9931

##### Fax

+98 44 3346 9935

##### Email

pashae.m@umsu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Dr Saber gholizadeh

##### Street address

Urmia University of Medical Sciences; Resalat Blvd.,  
Urmia, Iran

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5714783734

##### Phone

+98 21 8753 2210

##### Email

saber@umsu.ac.ir

##### 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

##### Street address

Imam Khomeini Hospital, Ershad Blvd., Urmia, Iran

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## Person responsible for scientific 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

**Contact**

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Fatemeh Maleki Sedgi

**Position**

MSc Student of Nutrition

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

Department of Nutrition, School of Medicine, Urmia

University of Medical Science, 11th km of Nazloo

Highway, Urmia

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5715799313

**Phone**

+98 44 3275 2375

**Email**

F.maleki1998@gmail

## 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