

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 2026

### The effect of garlic powder supplementation on body composition, liver echogenicity, insulin resistance, liver enzymes, lipid profile and oxidative stress in patients with non alcoholic fatty liver disease

#### Protocol summary

##### Study aim

Determine The effect of garlic powder supplementation on body composition, liver echogenicity, insulin resistance, liver enzymes, lipid profile and oxidative stress in patients with non alcoholic fatty liver disease

##### Design

Clinical trial with control group, parallel groups, double blind, randomised

##### Settings and conduct

The present study aiming to evaluate The effect of garlic powder supplementation on body composition, liver echogenicity, insulin resistance, liver enzymes, lipid profile and oxidative stress in patients with non alcoholic fatty liver disease. this study will be conducted in imam khomeini hospital in urmia. This study is a double blinded parallel randomized controlled clinical trial. 90 Patients will be randomly allocated into two groups, including intervention group and the control group. in this study participants and investigator are in blinding protocol.

##### Participants/Inclusion and exclusion criteria

nclusion criteria: contracting non alcoholic fatty liver disease and age of between 18 and 75. Exclusion criteria: alcohol use; viral hepatitis; hepatocellular carcinoma; other causes of chronic liver disease; diabetes mellitus; untreated hypothyroidism; psychiatric disorder; kidney disease; pregnancy; and lactation; subjects with low blood pressure; allergy to garlic

##### Intervention groups

The intervention group will be consume 4 tablets of 400 milligrams per day garlic in addition to usual treatment for three months. The control group will be consume 4 tablets of 400 milligrams per day placebo in addition to usual treatment for three months.

##### Main outcome variables

body composition; liver echogenicity; insulin resistance; liver enzymes; lipid profile; oxidative stress; systolic and diastolic blood pressure; intestinal function; Quantity of

appetite; fatty liver index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170206032417N4**

Registration date: **2019-04-28, 1398/02/08**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-04-28, 1398/02/08**

Update count: **0**

##### Registration date

2019-04-28, 1398/02/08

##### Registrant information

##### Name

Mohammad Alizadeh

##### Name of organization / entity

Urmia University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3275 2375

##### Email address

alizadeh.m@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-10-23, 1397/08/01

##### Expected recruitment end date

2020-10-22, 1399/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty  
**Trial completion date**  
empty

**Scientific title**  
The effect of garlic powder supplementation on body composition, liver echogenicity, insulin resistance, liver enzymes, lipid profile and oxidative stress in patients with non alcoholic fatty liver disease

**Public title**  
Effect of garlic powder in treatment of non alcoholic fatty liver

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**  
patients with non alcoholic fatty liver disease age of between 18 and 75

**Exclusion criteria:**  
alcohol use viral hepatitis hepatocellular carcinoma other causes of chronic liver disease diabetes mellitus untreated hypothyroidism psychiatric disorder kidney disease pregnancy lactation allergy to garlic patients with low blood pressure

**Age**  
From **18 years** old to **75 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
Target sample size: **90**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Non-Alcoholic Fatty liver patients referred to the gastroenterology clinic of Imam Khomeini Hospital of Urmia were selected consecutively on the basis of inclusion and exclusion criteria from the date of 23 September until 22 December in year of 2018. The subjects that selected, randomly (using 45 cards 1 and 45 numbered 2 cards to the number of patients present in the study and randomly selecting the cards by the patients) divided into two groups of intervention (1) and control (2). for double blinding, at the start of the study, in order to avoid any knowledge of the type of tablet taken by each group, the total number of packets containing garlic and placebo tablets by a person other than the researcher is encode in the form 1 and 2 and then are Available to the researcher.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
patient and investigator

**Placebo**  
Used

**Assignment**

Parallel  
**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Urmia University of Medical Sciences

**Street address**

Urmia University of Medical Sciences, orjans valley, Resalat boulevard

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5714783734

**Approval date**

2018-09-05, 1397/06/14

**Ethics committee reference number**

IR.UMSU.REC.1397.199

**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, 6, 12

**Method of measurement**

scale. kg

**2**

**Description**

body mass index

**Timepoint**

At weeks 0, 6, 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, 6, 12  
**Method of measurement**  
Enzymatic method , IU\ Lit

#### 4

**Description**  
ALP  
**Timepoint**  
At weeks 0, 6, 12  
**Method of measurement**  
Enzymatic method , IU\ Lit

#### 5

**Description**  
Aspartat transaminase  
**Timepoint**  
At weeks 0, 6, 12  
**Method of measurement**  
Enzymatic method, IU\ Lit

#### 6

**Description**  
Alanine Aminotransferase  
**Timepoint**  
At weeks 0, 6, 12  
**Method of measurement**  
Enzymatic method, IU\ Lit

#### 7

**Description**  
Fasting blood sugar  
**Timepoint**  
At weeks 0, 6, 12  
**Method of measurement**  
Enzymatic method, IU\ Lit

#### 8

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

#### 9

**Description**  
Body fat mass  
**Timepoint**  
At weeks 0, 6, 12  
**Method of measurement**  
BIA, kg

#### 10

**Description**  
Skeletal muscle mass

**Timepoint**  
At weeks 0, 6, 12  
**Method of measurement**  
BIA, kg

#### 11

**Description**  
Waist circumference  
**Timepoint**  
At weeks 0, 6, 12  
**Method of measurement**  
BIA, cm

#### 12

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

#### 13

**Description**  
HDL cholesterol  
**Timepoint**  
At weeks 0, 6, 12  
**Method of measurement**  
Enzymatic method, mg/dl

#### 14

**Description**  
Triglyceride  
**Timepoint**  
At weeks 0, 6, 12  
**Method of measurement**  
Enzymatic method, mg/dl

#### 15

**Description**  
LDL cholesterol  
**Timepoint**  
At weeks 0, 6, 12  
**Method of measurement**  
Enzymatic method, mg/dl

#### 16

**Description**  
Total cholesterol  
**Timepoint**  
At weeks 0, 6, 12  
**Method of measurement**  
Enzymatic method, mg/dl

#### 17

**Description**  
Total antioxidant capacity  
**Timepoint**

At weeks 0, 12

**Method of measurement**  
spectrophotometry, Nmol/l

## 18

**Description**  
SOD

**Timepoint**  
At weeks 0, 12

**Method of measurement**  
spectrophotometry, Nmol/l

## 19

**Description**  
MDA

**Timepoint**  
At weeks 0, 12

**Method of measurement**  
spectrophotometry, Nmol/l

## 20

**Description**  
Systolic blood pressure

**Timepoint**  
At weeks 0, 6, 12

**Method of measurement**  
Mercury sphygmomanometer, mmHg

## 21

**Description**  
Diastolic blood pressure

**Timepoint**  
At weeks 0, 6, 12

**Method of measurement**  
Mercury sphygmomanometer, mmHg

## 22

**Description**  
FATTY LIVER INDEX

**Timepoint**  
At weeks 0, 6, 12

**Method of measurement**  
Formula

## 23

**Description**  
Quantity of appetite

**Timepoint**  
At weeks 0, 6, 12

**Method of measurement**  
VAS questionnaire

## 24

**Description**  
Intestinal function

**Timepoint**  
At weeks 0, 6, 12

**Method of measurement**  
Bristol stool questionnaire

## 25

**Description**  
HOMA-IR

**Timepoint**  
At weeks 0, 12

**Method of measurement**  
Formula

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

**Description**  
Intervention group: The intervention group will be consume 4 tablets of 400 miligrams per day garlic in addition to usual treatment for three months.

**Category**  
Treatment - Drugs

### 2

**Description**  
Control group: The control group will be consume 4 tablets of 400 miligrams per day placebo in addition to usual treatment for three months.

**Category**  
Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

**Name of recruitment center**

Imam Khomeini Hospital, Urmia

**Full name of responsible person**

Dr. Mohammad Reza mohammad hosseini azar

**Street address**

Ershad Blvd,Ayatollah Modarres Blvd, Urmia

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**Postal code**

5431234567

**Phone**

+98 44 3567 8549

**Email**

hosseiniazar@yahoo.com

## **Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research of Urmia University of Medical Sciences

**Full name of responsible person**

Dr Iraj Mohebbi

**Street address**

Orjhans Street, Resalat Blvd, Urmia

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**Province**

West Azarbaijan

**Postal code**

5714783734

**Phone**

+98 21 8753 2210

**Email**

irajmohebi@yahoo.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of Urmia 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**

Dr. Mohammad Alizadeh

**Position**

Specialty Doctorte Degree in Nutritioal Science/ Urmia University of Medical Sciences Associate Prof

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Nutrition Department, Faculty of Medicine, College of Medicine, Urmia University of Medical Science, 11th km of Nazloo Road, Urmia

**City**

urmia

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alizadeh.m@umsu.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Dr. Mohammad Alizadeh

**Position**

Specialty Doctorte Degree in Nutritioal Science/ Urmia University of Medical Sciences Associate Prof

**Latest degree**

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**Other areas of specialty/work**

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alizadeh.m@umsu.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

abbas ali sangouni

**Position**

MSc Student of nutrition

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

. Nutrition Department, Faculty of Medicine, College of Medicine, Urmia University of Medical Science, 11th km of Nazloo Road, Urmia

**City**

urmia

**Province**

West Azarbaijan

**Postal code**

5715799313

**Phone**

+98 44 3275 2375

**Email**

## 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