Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 miligrams per day garlic in addition to usual treatment for three months. The control group will be consume 4 tablets of 400 miligrams 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
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Iran (Islamic Republic of)
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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

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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)]2 , kg\m2

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 questionaire

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
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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

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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
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

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Specialty Doctorte Degree in Nutritioal Science/ Urmia University of Medical Sciences Associate Prof

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MSc Student of nutrition

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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