Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

The effect of garlic powder supplementation on Metabolic Syndrome components, Fatty liver index, Intestinal function and Appetite Control in patients with metabolic syndrome

Protocol summary

Study aim
The evaluation of The effect of garlic powder supplementation on Metabolic Syndrome components, Fatty liver index, Intestinal function and Appetite Control in military patients with metabolic syndrome referred to Taleghani Hospital of Urmia

Design
Clinical trial with control group, parallel groups, double blind, randomised with 90 people sample size.

Settings and conduct
This study was performed as randomized, parallel controlled clinical trial on 90 patients with Metabolic Syndrome. In this study, while receiving written informed consent from patients, participants were blinded to receiving drugs and placebo.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age more than 18 y; subjects with metabolic syndrome according to ATP III guideline. Exclusion criteria: kidney disease; type 1 and 2 diabetes; psychiatric disorder; cancers; pregnancy and lactation; using blood pressure lower, blood sugar lower and anticoagulant drugs; allergy to garlic

Intervention groups
The intervention group: consume 4 tablets of 400 miligrams per day garlic The control group: consume 4 tablets of 400 miligrams per day placebo

Main outcome variables
body composition; insulin resistance; lipid profile; systolic and diastolic blood pressure; intestinal function; Quantity of appetite; fatty liver index

General information

Reason for update
We added secondary outcomes.

Acronym

IRCT registration information
IRCT registration number: **IRCT20180201038585N6**
Registration date: **2020-02-22, 1398/12/03**
Registration timing: **retrospective**

Last update: **2021-11-24, 1400/09/03**
Update count: **2**

Registration date
2020-02-22, 1398/12/03

Registrant information

Name
Karim Parastouei

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8248 3516

Email address
parastouei@bmsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-20, 1398/08/29

Expected recruitment end date
2020-02-18, 1398/11/29

Actual recruitment start date
2019-11-20, 1398/08/29

Actual recruitment end date
2020-02-18, 1398/11/29

Trial completion date
2020-05-19, 1399/02/30

Scientific title
The effect of garlic powder supplementation on Metabolic Syndrome components, Fatty liver index, Intestinal function and Appetite Control in patients with metabolic

syndrome

Public title
Effect of garlic in improvement of metabolic syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age more than 18 y Diagnosis of metabolic syndrome
Exclusion criteria:
Kidney disease Cardiovascular disease Type 1 and 2 diabetes Cancers Using blood pressure lower drugs Using blood sugar lower drugs Using anticoagulant drugs Psychiatric disorders Pregnancy and Lactation Allergy to garlic
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Actual sample size reached: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization lists were computer-generated by a statistician, then, participants assigned to the groups of the study. A trained person, randomly allocated and assigned the participants to study groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
intervention and randomization were performed through a random allocation list by a member of the research team as the only blinded individual to the assignment. Other members of the research team (including team leader and study coordinator), as well as all participants, were randomly assigned to groups and intervention and remained blind until the end of the
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of bahgeyatlah University of Medical Sciences
Street address
Moulla Sadra Ave , Vannak Square
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2019-07-09, 1398/04/18
Ethics committee reference number
IR.BMSU.REC.1398.120

Health conditions studied

1

Description of health condition studied
METABOLIC SYNDROME
ICD-10 code
E00-E90
ICD-10 code description
Endocrine, nutritional and metabolic diseases

Primary outcomes

1

Description
HDL cholesterol
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Enzymatic method, mg/dl

Secondary outcomes

1

Description
Weight
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Scale, kg

2

Description
Body mass index
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement

Weight(kg)\[height(m)]2 , kg\m2

3

Description
Waist Circumference
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
BIA, cm

4

Description
Body fat percent
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
BIA

5

Description
Triglyceride
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Enzymatic method, mg/dl

6

Description
LDL cholesterol
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Enzymatic method, mg/dl

7

Description
Total cholesterol
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Enzymatic method, mg/dl

8

Description
Systolic blood pressure
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Mercury sphygmomanometer, mmHg

9

Description
Diastolic blood pressure
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Mercury sphygmomanometer, mmHg

10

Description
Fatty liver index
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Formula

11

Description
Quantity of appetite
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
VAS questionnaire

12

Description
Intestinal function
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Bristol stool questionaire

13

Description
Fasting blood sugar
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Enzymatic method, IU\ Lit

14

Description
Serum insulin
Timepoint
at the beginning of the study (before intervention), and 12 weeks after intervention
Method of measurement
Radioimmunoassay

15

Description
HOMA-IR

Timepoint
at the beginning of the study (before intervention), and 12 weeks after intervention
Method of measurement
Formula

16

Description
Cardiometabolic index
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Formula

17

Description
Atherogenic index of plasma
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Formula

18

Description
Atherogenic coefficient
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Formula

19

Description
Castelli risk index I
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Formula

20

Description
Castelli risk index II
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Formula

21

Description
Visceral adiposity index
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Formula

22

Description
Lipid aaccumulation product
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Formula

23

Description
waist to height ratio
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Formula

24

Description
ABSI Index
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Formula

25

Description
BRI index
Timepoint
at the beginning of the study (before intervention), 6 and 12 weeks after intervention
Method of measurement
Formula

Intervention groups

1

Description
Intervention group: The intervention group will be consume 4 tablets of 400 miligrams per day garlic.
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
Taleghani hospital, urmia
Full name of responsible person
Abbas Ali Sangouni
Street address
Kashani Ave
City
Urmia
Province
West Azarbaijan
Postal code
9314836974
Phone
+98 44 3348 7990
Email
abassangoni03@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Ali Shiri
Street address
Mollasadra Ave, Vanak Sq, Tehran
City
Tehran
Province
Tehran
Postal code
1435915371
Phone
+98 21 8248 3516
Email
shira.reza@yahoo.com

Grant name

Grant code / Reference number

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

Title of funding source
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
karim Parastouei
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Mullasadra Ave, Vannak Sq,Tehran
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8248 3264
Email
karimparastouei@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Karim Parastouei
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Mullasadra Ave, Vannak Sq, Tehran
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+981435916471
Email
Karimparastouei@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Karim Parastouei
Position
Assistant professor

Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Mullasadra Ave, Vannak Sq, Tehran
City
Tehran
Province
Tehran
Postal code
1435916471
Phone
+98 21 8248 3264
Email
Karimparastouei@gmail.com

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
No - There is not a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Not applicable