

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of black garlic consumption on weight, blood lipid profile/ index and body fat percentage of overweight people receiving low calorie diet- Clinical trial

#### Protocol summary

##### Study aim

Determining the effect of black garlic consumption on weight, blood lipid indices and body fat percentage of obese people receiving a low-calorie diet

##### Design

40 obese people will be selected and randomly assigned into two groups. The intervention group will be given 10 grams of black garlic daily. The control group is asked to refrain from consuming garlic and garlic products.

##### Settings and conduct

The aim is to investigate the effect of consuming black garlic on the weight and body fat of obese people. Black garlic will be purchased from authorized production establishments. Among the obese people referred to Shahid Mofteh Yasouj Nutrition Clinic, the eligible people who agree to participate in the study will be selected and randomly assigned to the group receiving the low-calorie diet with or without black garlic. The intervention time is 8 weeks. The project leader and the analyst will be blind to the groups until the end of the analysis.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: having a body mass index above 25, age above 18 years, agreeing to participate in the project. Exclusion criteria: history of consuming garlic in the last month, receiving weight-reducing drugs, having diabetes, allergy to garlic, pregnancy, non-compliance with the diet, use of drugs affecting weight, non-referral, non-regular consumption of black garlic in the intervention group and consumption of garlic and its products in the control group

##### Intervention groups

Intervention: 20 cases with BMI above 25 on a low-calorie diet with daily consumption of 10 grams black garlic. Control: 20 obese people with body mass index above 25 on a low-calorie diet without consumption of garlic and its products.

##### Main outcome variables

body weight; body fat percentage; serum total cholesterol; serum triglyceride; serum low-density lipoprotein; Serum high-density lipoprotein

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230820059190N1**

Registration date: **2023-09-02, 1402/06/11**

Registration timing: **prospective**

Last update: **2023-09-02, 1402/06/11**

Update count: **0**

##### Registration date

2023-09-02, 1402/06/11

##### Registrant information

##### Name

Janmohamad Malekzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 74 3322 3505

##### Email address

malekjmd@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-23, 1402/07/01

##### Expected recruitment end date

2024-03-20, 1403/01/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of black garlic consumption on weight, blood lipid profile/ index and body fat percentage of overweight people receiving low calorie diet- Clinical trial

**Public title**

Effects of black garlic on weight loss in obese people

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

No consumption of other garlic products in groups Not receiving weight-reducing drugs Not having diabetes and familial hyperlipidemia No allergy to black garlic

**Exclusion criteria:**

>30% non-compliance with the diet Taking drugs that affect weight during treatment Failure to refer for weight control Not receiving prescribed garlic orderly

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In case of agreement to participation in the project, the cases will be randomly assigned to one of the two intervention groups (receiving black garlic) and the control group(not receiving black garlic). The randomization method is to generate 20 random numbers from 1 to 40 by Excel software to be assigned to the intervention group and the remaining 20 numbers to be assigned to the control group. Cases will be numbered based on the order of referring and each will be assigned to the relevant group based on the related number. Both groups will be given a proportionate low-calorie diet, and the intervention group will be given 10 grams of black garlic daily in addition to the low-calorie diet. Body weight, body fat percentage and serum lipids (triglycerides, total cholesterol, HDL cholesterol and LDL cholesterol) are measured and compared at the beginning of the intervention and after 8 weeks of intervention.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The project manager and the statistician will not be aware of the given treatment

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Yasuj University of Medical Sciences

**Street address**

Shahid Motahari Blvd.,Yasouj University of Medical Sciences., Yasuj

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyerahmad

**Postal code**

7591741417

**Approval date**

2023-03-13, 1401/12/22

**Ethics committee reference number**

IR.YUMS.REC.1402.018

**Health conditions studied****1****Description of health condition studied**

obesity

**ICD-10 code**

E66.0

**ICD-10 code description**

Obesity due to excess calories

**Primary outcomes****1****Description**

Body Weight

**Timepoint**

At the beginning and two months after therapeutic intervention (low-calorie diet with or without black garlic)

**Method of measurement**

Accurate scale measuring 0.1 kg

**2****Description**

Body fat percent

**Timepoint**

At the beginning and two months after therapeutic intervention (low-calorie diet with or without black garlic)

## Method of measurement

Bioimpedance Measurement

## Secondary outcomes

### 1

#### Description

Serum total cholesterol

#### Timepoint

At the beginning of the study (Just before the start of the intervention) and 8 weeks after the start of consuming black garlic and a low-calorie diet

#### Method of measurement

Enzymatic Method

### 2

#### Description

Serum triglyceride

#### Timepoint

At the beginning of the study (Just before the start of the intervention) and 8 weeks after the start of consuming black garlic and a low-calorie diet

#### Method of measurement

Enzymatic Method

### 3

#### Description

Serum high density lipoprotein

#### Timepoint

At the beginning of the study (Just before the start of the intervention) and 8 weeks after the start of consuming black garlic and a low-calorie diet

#### Method of measurement

Enzymatic method

### 4

#### Description

Serum low density lipoprotein

#### Timepoint

At the beginning of the study (Just before the start of the intervention) and 8 weeks after the start of consuming black garlic and a low-calorie diet

#### Method of measurement

Estimating using freidwald formula

## Intervention groups

### 1

#### Description

Intervention group: The intervention group of 20 people will receive 10 grams of black garlic daily under a low-calorie diet for 8 weeks.

#### Category

Treatment - Other

### 2

#### Description

Control group: The control group will be 20 people who will be on a low-calorie diet without consuming black garlic product.

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kohgiluyeh Boyerahmad province. Yasuj city. Shahid Muftah Clinic

##### Full name of responsible person

Jan Mohammad Malekzadeh

##### Street address

Pasdaran St. - Shahid Muftah Clinic

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

7591741417

##### Phone

+98 917 341 3301

##### Email

malekjmd@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yasuj University of Medical Sciences

##### Full name of responsible person

Amin Hosseini Mutlaq

##### Street address

Yasuj- Shahid Motahari Boulevard- Yasuj University of Medical Sciences

##### City

Yasuj

##### Province

Kohgilouyeh-va-Boyerahmad

##### Postal code

7591741417

##### Phone

+98 74 3344 4079

##### Email

aminhomo@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Yasuj 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**

Yasouj University of Medical Sciences

**Full name of responsible person**

Gita Shafiei

**Position**

Bachelor degree in Nutrition Sciences

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nutrition

**Street address**

15 Imam Hossein Square, Golestan, Faculty of Health and Nutrition

**City**

Yasuj

**Province**

Kohgilouyeh-va-Boyerahmad

**Postal code**

7591875114

**Phone**

+98 74 3322 5519

**Email**

shafiei.g71@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Jan Mohammad Malekzadeh

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Yasouj University of Medical Sciences

**Full name of responsible person**

Jan Mohammad Malekzadeh

**Position**

Assistant Professor

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is 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

**Title and more details about the data/document**

Data on primary variables will be shareable after de-identifying individuals

**When the data will become available and for how long**

Just after publishing the paper up to one year after the results are published

**To whom data/document is available**

The data will only be available to researchers working in academic and scientific institutions and also health related sections

**Under which criteria data/document could be used**

Data will be allowed to be reanalyzed for use in secondary studies such as meta-analyses

**From where data/document is obtainable**

Jan Mohammad Malekzadeh, Yasouj University of Medical Sciences, Faculty of Health and Nutrition Email: malekjmd@yahoo.com

**What processes are involved for a request to access data/document**

After receiving approval from Yasouj University of Medical Sciences (one week to one month), the data will be sent to the applicant

**Comments**