Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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-Boyrahmad
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 garlik)
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 garlik)

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 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
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7591741417
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malekjmd@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Amin Hosseini Mutlaq
Street address
Yasuj- Shahid Motahari Boulevard- Yasuj University of Medical Sciences
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7591741417
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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
Yasouj 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

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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

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Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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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