Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effects of Garlic Extract(Dosage Form) on Blood Pressure in Pre-Hypertensive Individuals and Measuring Lipid Profiles and Nitric Oxide Metabolites in the Individuals

Protocol summary

Study aim

The aim of this study was to investigate the effect of garlic extract (dosage form) on blood pressure in prehypertensive individuals and to measure lipid profiles and nitric oxide metabolites in these individuals.

Design

Two arm parallel group randomised, double blinded, sham controlled clinical trial with 110 patients.

Settings and conduct

This double-blind randomized clinical trial (RCT) study was performed on pre-hypertensive individuals referred to Khorramabad Health Center in 1400. The study lasts for eight weeks. During this period, individuals in the treatment group will receive two capsules daily at a dose of 500 mg and individuals in the placebo group will receive two placebo capsules daily. Variables are measured once at the beginning of the study, once at the end of the fourth week and again at the end of the study. The individuals (both in the treatment group and the control group) will receive the drug in sealed envelopes that are coded. Coding is done by the design partner. The researcher as well as the volunteers do not know the contents of the envelopes, in other words, they are blind.

Participants/Inclusion and exclusion criteria

"People in their 30s and 70s (men and women) who have recently or at least three months been diagnosed with prehypertension" will be included in the study. People with sensitivity to garlic and its side effects; people with cardiovascular problems and diseases; Hypertensive patients; Diabetic patients; people who have recently had surgery or received anesthesia; people with blood disorders who are taking anticoagulants; people with a history of gallstones and history of hypoglycemia; and pregnant women and breastfeeding will not be included in this study.

Intervention groups

Treatment group: Recipient of 500 mg garlic capsule
Control group: Recipient of 500 mg placebo capsule

Main outcome variables

Blood pressure, Lipid profiles, Nitric oxide

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210815052186N1**
Registration date: **2021-09-05, 1400/06/14**
Registration timing: **prospective**

Last update: **2021-09-05, 1400/06/14**
Update count: **0**

Registration date

2021-09-05, 1400/06/14

Registrant information

Name

Elham Rahmatinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3332 3704

Email address

nazary2577@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-22, 1400/06/31

Expected recruitment end date

2021-10-01, 1400/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Garlic Extract(Dosage Form) on Blood Pressure in Pre-Hypertensive Individuals and Measuring Lipid Profiles and Nitric Oxide Metabolites in the Individuals

Public title

"The Effect of Garlic Extract on Lowering Blood Pressure in Prehypertensive Individuals"

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

"People in Their 30s and 70s (Men and Women) Who Have Recently or At Least Three Months Received a Diagnosis of Pre-hypertension"

Exclusion criteria:

People with Allergies to Garlic and its Side Effects People with Cardiovascular Problems and Diseases. Patients Who Have Previously been Diagnosed with High Blood Pressure and are Taking Antihypertensive Drugs. People with Diabetes. People who Have recently had surgery. People Who Have Recently Received Anesthetics. People with Blood Disorders Who are Taking Anticoagulants People with a History of Gallstones. People with a History of Hypoglycemia. Pregnant and Lactating Women

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to equalize the distribution of two important confounders of age and sex, classes based on these two variables are created as "age group 30 to 50 years / age group 50 to 70 years" and "men / women" and then randomly Block Randomization is divided into two groups of treatment and control. The size of each block is 4 items, so that 6 different combinations of 4 blocks are created and are selected randomly by placing the blocks. Using this method, the sample size in the two study arms will be equal (balance) and the difference between the two groups in terms of sample size will be a maximum of half a block (two people). Using this method of random allocation, maximum power can be expected in the study results.All tests will be performed using stata14 software.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, volunteers receiving medication are blind to the study. Also, the main researcher who has other roles such as patient care, data collection and analysis, and evaluation of outcomes is blind to the study.The patient will receive the drug (intervention or control) in sealed envelopes that are coded. Coding is done by the design partner and the researcher (who also has other roles) as well as the patient in relation to the contents of the envelope, They are blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

School of Medicine, Campus University of Medical Sciences, 4 km of Khorramabad-Borujerd road

City

Khorramabad

Province

Lorestan

Postal code

6815144316

Approval date

2021-07-05, 1400/04/14

Ethics committee reference number

IR.LUMS.REC.1400.102

Health conditions studied

1

Description of health condition studied

Prehypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Blood pressure (Systolic, Diastolic, Pulse pressure, Mean arterial pressure)

Timepoint

"Measurement of blood pressure at the beginning of the study (before the intervention) and 4 weeks after the intervention and at the end of the study (8 weeks after the start of the study)"

Method of measurement

"Mercury Barometer"

2

Description

Nitric oxide metabolite level

Timepoint

Before the intervention, four weeks after the intervention, end of the intervention (eight weeks after the intervention)

Method of measurement

Grace method

3

Description

Triglyceride

Timepoint

Before the intervention, four weeks after the intervention, end of the intervention (eight weeks after the intervention)

Method of measurement

Autoanalyzer device

4

Description

Cholesterol

Timepoint

Before the intervention, four weeks after the intervention, end of the intervention (eight weeks after the intervention)

Method of measurement

Autoanalyzer device

5

Description

Low Density Lipoprotein (LDL)

Timepoint

Before the intervention, four weeks after the intervention, end of the intervention (eight weeks after the intervention)

Method of measurement

Autoanalyzer device

6

Description

High Density Lipoprotein (HDL)

Timepoint

Before the intervention, four weeks after the intervention, end of the intervention (eight weeks after the intervention)

Method of measurement

Autoanalyzer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive a 500 mg capsule containing standardized garlic extract (allicin, The exact dose will be determined during the practical work), The study period will be eight weeks (56 days), the daily dose of the capsule for the intervention group is two per day.

Category

Treatment - Drugs

2

Description

Control group: The control or comparison group will receive a 500 mg capsule containing starch (containing 500 mg of starch).The study period will be eight weeks (56 days), the daily dose of the capsule for the control group is two per day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Health houses under the supervision of Khorramabad city health network

Full name of responsible person

Hossein Beiranvand

Street address

School of Medicine, Campus of Lorestan University of Medical Sciences, 4 km of Khorramabad-Borujerd road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person
Dr. Ebrahim Fallahi

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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
Khoram-Abad 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
Khoram-Abad University of Medical Sciences

Full name of responsible person
Afshin Nazari

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Physiology

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Person responsible for updating data

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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