

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the effect of the formulated ginger rhizome capsule on blood pressure in prehypertensive patients.

Protocol summary

Study aim

Investigation of the effect of the formulated ginger rhizome capsule on blood pressure in prehypertensive patients referred to Khorram Abad health center

Design

A clinical trial with randomized intervention and control groups

Settings and conduct

Patients aged between 30 to 70 years with systolic pressure between 120 and 139 and diastolic between 80 and 89 mmHg are randomly divided into two groups of intervention and control. The intervention group will receive capsules containing 26 mg of gingerol and the placebo group will receive capsules containing 400 mg of wheat starch. Then, blood pressure and its clinical consequences will be examined. The patient's blood pressure and other relevant variables including systolic, diastolic, mean arterial pressure, and pulse pressure are measured using a digital sphygmomanometer. Also, cholesterol, triglycerides, LDL, and HDL are measured by taking blood samples from patients and using an autoanalyzer in Ashair Khorramabad Hospital. Nitric Oxide Assay Kit and ELISA reader are used to measuring NO.

Participants/Inclusion and exclusion criteria

Inclusion criteria include patients aged between 30-70 years with the diagnosis of prehypertension and hyperlipidemia recently or at least during the last three months. Exclusion criteria include a history of high blood pressure or diabetes, taking blood pressure medications

Intervention groups

The intervention group received 26 mg daily gingerol capsule in addition to the standard treatment regimen of the control group.

Main outcome variables

Decreased blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220821055757N1**

Registration date: **2023-04-10, 1402/01/21**

Registration timing: **retrospective**

Last update: **2023-04-10, 1402/01/21**

Update count: **0**

Registration date

2023-04-10, 1402/01/21

Registrant information

Name

Hossein Beiranvand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3327 3230

Email address

beiranvand_hossein@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of the formulated ginger rhizome capsule on blood pressure in prehypertensive patients.

Public title

Investigating the effect of ginger capsules on blood pressure.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who have received a diagnosis of hypertension within the maximum last three months. Patient consent to enter the study. The age of the patients is between 30 and 70 years.

Exclusion criteria:

Patients with diabetes. Patients with high blood pressure. Patients with blood disorders.

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into two groups using the stratified blocked randomization method. In this way, considering the gender (female, male), a stratum will be formed and within this stratum, the samples in the form of four blocks will be randomly assigned to the desired groups. classes are considered in order to match the two study groups of gender and BMI (thin and normal, obese and overweight). in this study, four classes are formed and the samples are randomly assigned to the subject group in the form of blocks of four. study will be assigned. in the present study, 76 people were treated, 38 patients were treated with the original drug and 38 patients were treated with placebo. In this study, the 4-layer randomized block method is used to randomly assign patients to two groups A (drug group) and group B (control group). To do this, first by considering the classes as the age range (70-30) and over 70 years within each class, a list of blocks is written and numbers are assigned to them. (AABB (1) - ABAB (2) - ABBA (3) - BBAA (4) - BABA (5) - BAAB (6)). Then, using a table of random numbers, the numbers between one to 6 (for example, 1,4,5, etc.) are randomly selected, and finally the list of treatment assignments will be formed based on a sequence of letters A and B.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double blind and the patient, the

treatment evaluator are unaware of the experimental group. medicines are made in the same way, the patient and the person who gives the medicine to the patient have no information about the type and content of the medicine.

Placebo

Used

Assignment

Parallel

Other design features

Prevention of high blood pressure, without complications and acceptable to patients.

Secondary Ids

empty

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

Ethics committee of Lorestan University of Medical Sciences

Street address

Lorestan, Khorramabad, 3 km of Khorramabad Road, Tehran, Pardis University Complex, Vice Chancellor for Research and Technology, Lorestan University of Medical Sciences, Office of Research Ethics Committee

City

Khorramabad

Province

Lorestan

Postal code

6876166145

Approval date

2021-01-20, 1399/11/01

Ethics committee reference number

IR.LUMS.REC.1399.271

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

Prehypertension

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Systolic and diastolic blood pressure (main variable)

Timepoint

At the beginning of the study (before intervention) and 4, 8 weeks after the start of taking ginger capsules

Method of measurement

Mercury sphygmomanometer

2

Description

Cholesterol

Timepoint

At the beginning of the study (before intervention) and 4, 8 weeks after the start of taking ginger capsules

Method of measurement

Chemistry Analyzer

3

Description

Triglycerides

Timepoint

At the beginning of the study (before intervention) and 4, 8 weeks after the start of taking ginger capsules

Method of measurement

Chemistry Analyzer

4

Description

Low Density Lipoprotein (LDL)

Timepoint

At the beginning of the study (before intervention) and 4, 8 weeks after the start of taking ginger capsules

Method of measurement

Chemistry Analyzer

5

Description

Nitric oxide metabolites

Timepoint

At the beginning of the study (before intervention) and 4, 8 weeks after the start of taking ginger capsules

Method of measurement

Nitric oxide assay kit

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group: In this group, a capsule containing 26 mg of the active constituents gingerol is used at a daily dose of 1 capsule for 2 months (After purchasing the gingerol standard kit from KIA ZIST Hamedan company, the capsules were prepared in the laboratory of Khorram Abad Faculty of Pharmacy).

Category

Treatment - Drugs

2

Description

Control group: Actually, they are the placebo group, which have the characteristics of the intervention group,

but they receive capsules containing 400 mg of wheat starch.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Khorramabad health center

Full name of responsible person

Hossein Beiranvand

Street address

Lorestan, Khorramabad, Razi St., Khorramabad health center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

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Lorestan, Khorramabad, Kamalvand, km 4 of Khorramabad road

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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

40

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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

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Position

Official

Latest degree

Master

Other areas of specialty/work

Physiology

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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