Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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)
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+98 66 3327 3230
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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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Email
m.h.Khorramabad @lums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Bahram Rasoulian
Street address
Lorestan, Khorramabad, Kamalvand, km 4 of Khorramabad road
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381351698
Phone
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Email
Rasoulian.b@lums.ac.ir
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

Person responsible for general inquiries

Contact
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Hossein Beiranvand
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