Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Fortification of chocolate with microencapsulated garlic extract and consumption effects of the product on blood pressure, serum lipid profile, inflammatory and oxidative stress indices in patients with hypertension

Protocol summary

Study aim
Fortification of chocolate with microencapsulated garlic extract and consumption effects of the product on blood pressure, serum lipid profile, inflammatory and oxidative stress indices in patients with hypertension

Design
A double blind cross-over controlled randomized trial

Settings and conduct
Shiraz, Emem reza Clinic

Participants/Inclusion and exclusion criteria
1. Systolic blood pressure >= 130 mmHg or Diastolic blood pressure >= 80 mmHg or both 2. Age range between 24 and 65 years (Adults) 3. Not being in pregnancy or lactation periods 4. Not being affected by diabetes or thyroid disorders 5. No consumption of anticoagulant drugs 6. No dietary supplementation 7. Shiraz residence 8. Participation willingness

Intervention groups
In this cross-over clinical trial, there will be two groups namely intervention and control within each of which 22 eligible individuals (men and women). Participants in intervention and control group will receive 10 grams of intervention and control of chocolate per day for six weeks, respectively. Then, patients will start wash-out period for three weeks. Participants will receive no type of chocolate in this period. After the end of the wash-out period, the second half of the study begins, but this time the participants of each group will receive the opposite chocolates for next six weeks.

Main outcome variables
Blood pressure and serum levels of triglycerides, total cholesterol, LDL, HDL, homocysteine, hsCRP and malondialdehyde

General information

Reason for update

Acronym
شکلات غنی شده با عصاره بوزدایی شده سیر و فشارخون

IRCT registration information
IRCT registration number: **IRCT20150201020891N2**
Registration date: **2019-06-23, 1398/04/02**
Registration timing: **prospective**

Last update: **2019-06-23, 1398/04/02**
Update count: **0**

Registration date
2019-06-23, 1398/04/02

Registrant information

Name
Salman Mohammadi
Name of organization / entity
Lorestan University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 66 3340 8176
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s.mohammadi.diet@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-08-23, 1398/06/01

Expected recruitment end date
2019-09-11, 1398/06/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Fortification of chocolate with microencapsulated garlic extract and consumption effects of the product on blood pressure, serum lipid profile, inflammatory and oxidative stress indices in patients with hypertension

Public title
Fortification of chocolate with microencapsulated garlic extract and consumption effects of the product on blood pressure, serum lipid profile, inflammatory and oxidative stress indices in patients with hypertension

Purpose
Other

Inclusion/Exclusion criteria
Inclusion criteria:
Systolic blood pressure >= 130 mmHg or Diastolic blood pressure >= 80 mmHg OR both Shiraz residence Participation willingness
Exclusion criteria:
Being in pregnancy or lactation periods Affected with diabetes or thyroid disorders Anticoagulant drug consumption Dietary supplementation of any type

Age
From **24 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
For blocked randomization, 4 blocks with 11 capacities will be created. These blocks, then, stratified in 2 strata based on gender. This block randomization with gender stratification matches two groups for total number of male and female participants.

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to blinding, Both types of chocolates are made in a Chocolate manufacturing factory under supervision of the technical assistant. Then, both intervention and placebo chocolates are packed in the same covers with different labeling: A or B. Technical assistant of the factory and thesis supervisor are the only individuals informed about the content of different labels.

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Zand street
City
Shiraz
Province
Fars
Postal code
7135744488

Approval date
2019-06-12, 1398/03/22

Ethics committee reference number
IR.SUMS.REC.1398.462

Health conditions studied

1

Description of health condition studied
Hypertension

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Hypertension

Timepoint
The beginning of the study and the end of the sixth, ninth and fifth weeks

Method of measurement
Digital barometer

2

Description
Serum lipid levels

Timepoint
The beginning of the study and the end of the sixth, ninth and fifth weeks

Method of measurement
ELISA kits

3

Description
Serum hsCRP level

Timepoint
The beginning of the study and the end of the sixth, ninth and fifth weeks

Method of measurement

RIA kit

4

Description
Serum malondealdehyde levels
Timepoint
The beginning of the study and the end of the sixth, ninth and fifth weeks
Method of measurement
Spectrophotometry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Daily consumption of 10 grams of bitter chocolate (60 percent) enriched with deodorized Garlic extract powder (equivalent to 4 grams of fresh garlic) for six weeks
Category
Treatment - Other

2

Description
Control group: Daily consumption of 10 grams of bitter chocolate (60 percent) enriched with maltodextrin for six weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emamreza Sub-specialty Clinic
Full name of responsible person
Salman Mohammadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Younes Ghasemi
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Salman Mohammadi
Position
PhD Student
Latest degree
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Title and more details about the data/document
In this study, only a fraction of the data, including information about the main outcome, can be shared and other personal information of patients whose publication does not have an impact on the interpretation of the results will not be shared.
When the data will become available and for how long
Starting the access period from the summer of 2020
To whom data/document is available
Access to data from this study will only be possible for academic researchers.
Under which criteria data/document could be used
To use the data from this study, a research proposal submission will be required.
From where data/document is obtainable
Refer to the scientific accountability authorities for which the specifications were previously provided.
What processes are involved for a request to access data/document
To access to the present study's documentations, a research proposal is sufficient.
Comments