

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 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  $\geq$  130 mmHg or Diastolic blood pressure  $\geq$  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)

###### Phone

+98 66 3340 8176

###### Email address

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  $\geq$  130 mmHg or Diastolic blood pressure  $\geq$  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 malonaldehyde 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

###### **Street address**

Zand Street

###### **City**

Shiraz

###### **Province**

Fars

###### **Postal code**

7135744488

###### **Phone**

+98 71 3212 2460

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###### **Email**

s.mohammadi.diet@gmail.com

###### **Web page address**

#### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Shiraz University of Medical Sciences

###### **Full name of responsible person**

Younes Ghasemi

###### **Street address**

Zand Street

###### **City**

Shiraz

###### **Province**

Fars

###### **Postal code**

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###### **Phone**

+98 71 3212 2460

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###### **Email**

s.mohammadi.diet@gmail.com

##### **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**

Master

###### **Other areas of specialty/work**

Nutrition

###### **Street address**

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###### **Province**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Salman Mohammadi

**Position**

PhD Student

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

Salman Mohammadi

**Position**

PhD Student

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

Zand Street

**City**

Shiraz

**Province**

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**Postal code**

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**Phone**

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**Email**

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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**