Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Evaluation of efficacy of Resveratrol on hypertension, a randomized cross-over double- blinded placebo-controlled trial

Protocol summary

Summary

Background: The aim of this study is to evaluate the efficacy of resveratrol (trans-3, 5, 4’-trihydroxystilbene, a polyphenol present in grapes) in comparison with the placebo on blood pressure in participants with pre- and stage-1 hypertension. Design and Methods:In a randomized, double blind, placebo-controlled study, 50 participants with pre-hypertension (diastolic blood pressure and systolic blood pressure, 80- 89 mmHg and 120-139 mmHg, respectively) and 50 participants with stage 1 hypertension (diastolic and systolic, 90-99 mmHg and 140-159 mmHg, respectively) will be assigned to sequence A or B to receive resveratrol (99% pure from BIOTIVIA LONGEVITY BIOCEUTICALS LLC Company, USA, in 500 mg capsules, twice daily for 4 weeks, orally) or placebo (500 mg neutral micro cellulose capsules, twice daily for 4 weeks) in a 2×2 cross-over design (4 weeks treatment-4 weeks washout-4 weeks treatment). The participants’ blood pressure will be recorded (the average of two times within 15 minute interval) every week during the study. The participants in the pre-hypertensive group will not have any medication, while those in the stage 1 hypertensive group will continue to receive their routine medications during the study. Blood samples will be taken from all groups and examined for various biochemical parameters.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407078129N7**
Registration date: **2014-08-15, 1393/05/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-08-15, 1393/05/24

Registrant information

Name
Ali Movahed
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Department of Research, Bushehr University of Medical Sciences

Expected recruitment start date

2015-09-20, 1394/06/29

Expected recruitment end date

2016-09-19, 1395/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of Resveratrol on hypertension, a randomized cross-over double- blinded placebo-controlled trial

Public title

Efficacy of resveratrol in patients with pre and first stage hypertension

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Pre-hypertensive(average of two times

measurement with an interval of 15 minutes, diastolic and systolic blood pressure(80-89mmHg, 120-139 mmHg respectively) • Stage 1 hypertensive (average of two times measurement with an interval of 15 minutes (diastolic and systolic blood pressure 90-99 mmHg, 140-159 mmHg, respectively) • Male or Female • Age between 20 and 60-years • Ability to provide informed consent Exclusion Criteria:Approved or doubtful secondary hypertension; History of chronic or acute kidney Disease; History of heart failure; History of chronic or acute liver diseases; History of diabetes mellitus; History of prior cardiovascular events (Acute Myocardial Infarction, Cardiovascular diseases, Percutaneous Coronary Angioplasty or Coronary Artery Bypass Graft); Pregnancy or breast feeding;Blood arterial pressure >160/110

Age
From **30 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features
Randomization: A stratified complete block randomization method will be used in this trial.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Bushehr University of Medical Sciences

Street address
Director of Research, Pardis site, Next to Salmon Farsi Hospital, Bushehr University of Medical Sciences

City
Bushehr

Postal code
751472537

Approval date
2014-07-07, 1393/04/16

Ethics committee reference number
B-93-4-16

Health conditions studied

1

Description of health condition studied
Hypertension

ICD-10 code
I10-I15

ICD-10 code description
High Blood pressure

Primary outcomes

1

Description
Diastolic and systolic blood pressure

Timepoint
once in a week during intervention period

Method of measurement
A sphygmomanometer and Stethoscope will be used to measure the blood pressure, once in a week, and average of two times within 15 minutes will be recorded.

2

Description
Added at 2015-04-16: Mean arterial pressure

Timepoint
Added at 2015-04-16: once in a week during intervention

Method of measurement
Added at 2015-04-16: systolic blood BP plus 2 times diastolic BP divided by 3

Secondary outcomes

1

Description
PTT

Timepoint
Before and after the first stage intervention, after one month washout and after one month of second stage intervention

Method of measurement
By Reputed kits

2

Description
SGOT

Timepoint
Before and after the first stage intervention, after one month washout and after one month of second stage intervention

Method of measurement
By Kits and ELISA method

3

Description
SGPT
Timepoint
Before and after the first stage intervention, after one month washout and after one month of second stage intervention
Method of measurement
By Kits and ELISA method

4

Description
GGT
Timepoint
Before and after the first stage intervention, after one month washout and after one month of second stage intervention
Method of measurement
By Kits and ELISA method

5

Description
ALP
Timepoint
Before and after the first stage intervention, after one month washout and after one month of second stage intervention
Method of measurement
By Kits and ELISA method

6

Description
TG
Timepoint
Before and after the first stage intervention, after one month washout and after one month of second stage intervention
Method of measurement
By Reputed kits

7

Description
Cholesterol
Timepoint
Before and after the first stage intervention, after one month washout and after one month of second stage intervention
Method of measurement
By Reputed kits

8

Description
LDL
Timepoint
Before and after the first stage intervention, after one month washout and after one month of second stage intervention
Method of measurement
By Reputed kits

9

Description
HDL
Timepoint
Before and after the first stage intervention, after one month washout and after one month of second stage intervention
Method of measurement
By Reputed kits

10

Description
Hematocrit
Timepoint
Before and after the first stage intervention, after one month washout and after one month of second stage intervention
Method of measurement
By Reputed kits

11

Description
Albumin
Timepoint
Before and after the first stage intervention, after one month washout and after one month of second stage intervention
Method of measurement
Auto-analyzer (Spectrophotometry)

12

Description
platelets
Timepoint
Before and after the first stage intervention, after one month washout and after one month of second stage intervention
Method of measurement
By bleeding time test

13

Description
PT
Timepoint
Before and after the first stage intervention, after one month washout and after one month of second stage intervention
Method of measurement
By reputed kits

14

Description
Added at 2015-03-15: Bilirubin
Timepoint
Added at 2015-03-15: Before and after the first stage

intervention, after one month washout and after one mont of second intervention

Method of measurement

Added at 2015-03-15: Auto-analyzer

15

Description

Added at 2015-04-16: Angiotensin II

Timepoint

Added at 2015-04-16: Before and after the first stage intervention, after one month washout time and after one month of second stage intervention

Method of measurement

Added at 2015-04-16: By kits for ELISA method

16

Description

Added at 2015-04-16: Endothelin 1

Timepoint

Added at 2015-04-16: Before and after the first stage intervention, after one month washout time and after one month of second stage intervention

Method of measurement

Added at 2015-04-16: By kits for ELISA method

17

Description

Added at 2015-04-16: Nor-epinephrine

Timepoint

Added at 2015-04-16: Before and after the first stage intervention, after one month washout time and after one month of second stage intervention

Method of measurement

Added at 2015-04-16: By kits for ELISA method

18

Description

Added at 2015-04-16: TNF- α

Timepoint

Added at 2015-04-16: Before and after the first stage intervention, after one month washout time and after one month of second stage intervention

Method of measurement

Added at 2015-04-16: By kits for ELISA method

19

Description

Added at 2015-04-16: nitric oxide

Timepoint

Added at 2015-04-16: Before and after the first stage intervention, after one month washout and after one month of second stage intervention

Method of measurement

Added at 2015-04-16: By kits for ELISA method

20

Description

Added at 2015-04-16: Malondialdehyde-uRINARY ISOPROSTANE

Timepoint

Added at 2015-04-16: Before and after the first stage intervention, after one month washout time and after one month of second stage intervention

Method of measurement

Added at 2015-04-16: By kits for ELISA method

Intervention groups

1

Description

The intervention group, Resveratrol ,99% pure(500 mg twice a day) for a period of one month.

Category

Treatment - Drugs

2

Description

The Control group, placebo (500 mg neutral cellulose, twice a day) for a period of one month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bushehr University of Medical Sciences

Full name of responsible person

Ali Movahed

Street address

Biochemistry Laboratory, Faculty of Medicine, Moalem Street, Bushehr University of Medical Sciences.

City

Bushehr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research, Bushehr University of Medical Sciences

Full name of responsible person

Dr Ostovar

Street address

Research Department, Next to Salmon Farsi Hospital, Pardis Site, Bushehr Unibersity of Medical Sciences

City

Bushehr

Grant name

Grant code / Reference number

B-93-16-4

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Deputy of Research, Bushehr University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Bushehr University of Medical Sciences

Full name of responsible person

Ali Movahed

Position

Academic Member, PH.D

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty