Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

The protective Potential of resveratrol in the prevention and reduction of complications in patients undergoing elective coronary artery bypass grafting surgery

Protocol summary

Study aim
The aim of this study is to evaluate the protective Potential of resveratrol in the prevention and reduction of complications in patients undergoing elective coronary artery bypass grafting surgery

Design
In the form of clinical trial, double blinded study

Settings and conduct
The Heart Center, affiliated to Bushehr University of Medical Sciences,Iran

Participants/Inclusion and exclusion criteria
، Inclusion criteria: Intention of the patients to participate in the trial, patients on elective surgery, having no addiction to any drugs or alcohol, mental or psychological disorders and the age between 30 to 70 years. Exclusion criteria: history of having chronic kidney or liver disease, having heart surgery before

Intervention groups
Th the case group 250 mg capsules of resveratrol, two times a day for 60 days will be given. The control group will be without resveratrol.

Main outcome variables
Heart Function, including: Ejection Fraction, left ventricular function, ECG, blood pressure(diastolic and Systolic).

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20111119008129N12**
Registration date: **2022-06-18, 1401/03/28**
Registration timing: **prospective**

Last update: **2022-06-18, 1401/03/28**
Update count: **0**

Registration date
2022-06-18, 1401/03/28

Registrant information
Name
Ali Movahed
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 77 3332 4044
Email address
a.movahed@bpums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-06-20, 1401/03/30

Expected recruitment end date
2022-12-21, 1401/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The protective Potential of resveratrol in the prevention and reduction of complications in patients undergoing elective coronary artery bypass grafting surgery

Public title
Protective role of Resveratrol in Heart surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:

Intention of the patients to participate in the trial Patients on elective surgery Having no addiction to any drugs or alcohol Not having mental or psychological disorders Participants with the age between 30 to 70 years

Exclusion criteria:

History of having chronic kidney disease, History of having chronic liver disease Having heart surgery before

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **2**

The samples will be collected before and after the trial

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation method in this study will be permutated block randomization, where T represents the person receiving the intervention and C represents the person who receive the Placebo. This method is performed by considering blocks of sizes 4 patients so that the total number of 4 permutations is equal to 6 blocks as follows: (C,C,T,T), (T,T,C,C), (C,T,T,C), (C,T,C,T), (T,C,C,T), (T,C,T,C), (C,T,C,T) Then, a number of 15 blocks will be randomly selected with replacement from these 6 blocks. Finally, the desired list of 15 blocks of 4 (4 * 15 = 60 total number of samples) is generated and the order of assignment to each of the samples participating in the study is determined. These steps are performed using R software version 3.6.3

Blinding (investigator's opinion)

Double blinded

Blinding description

First, all resveratrol and placebo capsules are prepared in the same shape and size and in packs of 20 for distribution to patients. The resveratrol and placebo packages are then labeled based on computer-generated codes (without indication of its content). Each of these codes is determined based on the sequence of random allocation of individuals to groups. The project manager, the only person who is aware of the codes and the order in which individuals are assigned to groups, is not involved in any of the evaluation and measurement of outcomes steps. On the other hand, the shape, size, and type of packaging of the resveratrol and placebo are exactly the same, so the patient and the outcome evaluator will not know the type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Bushehr University of Medical Sciences, Bushehr, Iran

Street address

Moallem Street, Bushehr Medical University

City

Bushehr

Province

Boushehr

Postal code

987514633341

Approval date

2022-04-25, 1401/02/05

Ethics committee reference number

IR.BPUMS.REC.1401.024

Health conditions studied

1

Description of health condition studied

Diseases of the circulatory system

ICD-10 code

I24

ICD-10 code description

Ischemic heart diseases

Primary outcomes

1

Description

The heart function

Timepoint

Around 24 hours, before the start of Resveratrol consumption, and 12 to 24 hours after the period of 60 days of consumption

Method of measurement

By echocardiography

2

Description

Diastolic blood pressure

Timepoint

Around 24 hours, before the start of Resveratrol consumption, and 12 to 24 hours after the period of 60 days of consumption

Method of measurement

By sphygmomanometer, Mercury Type (Microlife

company)

3

Description
systolic blood pressure
Timepoint
Around 24 hours, before the start of Resveratrol consumption, and 12 to 24 hours after the period of 60 days of consumption
Method of measurement
By sphygmomanometer, Mercury Type (Microlife company)

Secondary outcomes

1

Description
Total Antioxidant Capacity(TAC)
Timepoint
Around 24 hours, before the start of Resveratrol consumption, and 24 to 72 hours after the period of 60 days of Resveratrol consumption
Method of measurement
By ELISA technique

2

Description
LDH (lactate dehydrogenase)
Timepoint
Around 24 hours, before the start of Resveratrol consumption, and 24 to 72 hours after the period of 60 days of Resveratrol consumption
Method of measurement
By reliable kits(By using spectrophotometry)

3

Description
TBRS
Timepoint
Around 24 hours, before the start of Resveratrol consumption, and 24 to 72 hours after the period of 60 days of Resveratrol consumption
Method of measurement
By ELISA technique

4

Description
CK-MB (creatine kinase MB)
Timepoint
Around 24 hours, before the start of Resveratrol consumption, and 24 to 72 hours after the period of 60 days of Resveratrol consumption
Method of measurement
By reliable kits(By using spectrophotometry)

5

Description
NO (Nitric oxide)
Timepoint
Around 24 hours, before the start of Resveratrol consumption, and 24 to 72 hours after the period of 60 days of Resveratrol consumption
Method of measurement
By ELISA technique

6

Description
TNF-α (tumor necrosis factor-α)
Timepoint
Around 24 hours, before the start of Resveratrol consumption, and 24 to 72 hours after the period of 60 days of Resveratrol consumption
Method of measurement
By ELISA technique

7

Description
hs-CRP (High-sensitivity C-reactive Protein)
Timepoint
Around 24 hours, before the start of Resveratrol consumption, and 24 to 72 hours after the period of 60 days of Resveratrol consumption
Method of measurement
By reliable kits(By using spectrophotometry)

Intervention groups

1

Description
Intervention group: To this group will be given 250 mg capsules of Resveratrol (98% pure, AllNatural, Nutritional INC, Winnipeg, Canada). two times a day, morning and evening for a period of 60 days.
Category
Prevention

2

Description
Control group: To this group, will be given 250 mg capsules of totally inert -microcellulose, Biotivia, Bioceuticals International Srl, Italy) and the routine medicines. And, all the examinations for heart function and blood examinations are done, exactly in the same way as the intervention group.Before and after the Trial.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
The Bushehr Heart Center, afiliated to Bushehr University of Medical Sciences, Bushehr, Iran

Full name of responsible person
Ali Movahed
Street address
Moallem Street, Bushehr Heart Center,
City
Bushehr
Province
Boushehr
Postal code
987514633341
Phone
+98 917 371 1063
Email
a.movahed@BPUMS.AC.IR

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Boushehr University of Medical Sciences
Full name of responsible person
Akram Farhadi
Street address
Bushehr University of Medical Sciences, Department of Research, Salmon Farsi Street, Bahmani, Bushehr, Iran.
City
Bushehr
Province
Boushehr
Postal code
987518759577
Phone
+98 77 3345 0178
Email
Research@BPUMS.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Boushehr 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
Boushehr University of Medical Sciences
Full name of responsible person
Ali Movahed
Position
Academic Member
Latest degree
Ph.D.
Other areas of specialty/work
Biochemistry
Street address
Moallem ST, Faculty of Medicine, Biochemistry Laboratory, Bushehr Universirty Of Medical Sciences, Bushehr, Iran.
City
Bushehr
Province
Boushehr
Postal code
987514633341
Phone
+98 77 3332 4044
Email
a.movahed@BPUMS.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Boushehr University of Medical Sciences
Full name of responsible person
Ali Movahed
Position
Academic Member,
Latest degree
Ph.D.
Other areas of specialty/work
Biochemistry
Street address
Moallem ST, Faculty of Medicine, Biochemistry Lab, Bushehr Universirty of Medical Sciences, Bushehr, Iran
City
Bushehr
Province
Boushehr
Postal code
987514633341
Phone
+98 77 3332 4044
Email
a.movahed@BPUMS.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Boushehr University of Medical Sciences
Full name of responsible person
Ali Movahed
Position
Academic Member
Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Biochemistry Lab, Faculty of Medicine, Bushehr University of Medical Sciences, Moallem ST, Bushehr, Iran

City

Bushehr

Province

Boushehr

Postal code

987514633341

Phone

+98 77 3332 4044

Email

a.movahed@BPUMS.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The Deputy of Research is responsible to provide the information and documents to the participants in the Trial.

When the data will become available and for how long

After the trial was over and the results were analyzed, for a period of one year, access to the document is possible.

To whom data/document is available

The principal investigator, the participants undergone the trial, deputy of research and technology.

Under which criteria data/document could be used

1- If the researcher wants the document to use in the following research. 2- The patients who want to know about the results of the examination

From where data/document is obtainable

The main investigator or responsible for the trial, or the deputy of Research should be contacted.

What processes are involved for a request to access data/document

A request letter to be given to the main investigator, or the Deputy of Research to be consider.

Comments