Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Studying the effect of resveratrol compared to placebo on ventricular and supraventricular arrhythmias in patients with implantable cardiac defibrillators

Protocol summary

Study aim
Evaluation of the effects of resveratrol on the rate of ventricular and supraventricular arrhythmias in patients with Implantable Cardioverter Defibrillator (ICD).

Design
A control, parallel-group, double-blind, randomize, phase 3 clinical trial on 160 patients. The website www.sealedenvelope.com will be used for randomization.

Settings and conduct
In this study, 160 patients with ICD devices who complete the inclusion criteria and exclusion criteria and enter the project with informed consent randomly and blindly assign to the intervention or control group after receiving information and performing the necessary laboratory tests. Study location: Dr. Tayyibi's office

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age over 18 years; Having an ICD for more than 3 months before starting participation in the plan; Obtaining informed consent from the patient. Exclusion criteria: Taking resveratrol capsules beforehand; Severe renal dysfunction(GFR < 30 ml/min/1.73m2); Significant impairment in liver function(Child-Pugh class B or C).

Intervention groups
The intervention group: taking 250 mg resveratrol capsules, one capsule daily for 3 months. The control group: taking a placebo, one capsule daily, for three months.

Main outcome variables
Proportion of supraventricular and ventricular arrhythmias recorded by ICD over 3 months

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120520009801N17**
Registration date: **2025-07-18, 1404/04/27**
Registration timing: **prospective**

Last update: **2025-07-18, 1404/04/27**
Update count: **0**

Registration date
2025-07-18, 1404/04/27

Registrant information

Name
Amir Hooshang Mohammadpour
Name of organization / entity
Mashhad University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 51 1882 3255
Email address
mohamadpoorah@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-06, 1404/05/15

Expected recruitment end date
2026-03-20, 1404/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Studying the effect of resveratrol compared to placebo on ventricular and supraventricular arrhythmias in

patients with implantable cardiac defibrillators

Public title
Resveratrol effect on ventricular and supraventricular arrhythmias
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Having an ICD for more than 3 months before starting participation in the study Obtaining informed consent from the patient
Exclusion criteria:
Taking resveratrol capsules beforehand Severe renal dysfunction(GFR < 30 ml/ min/1.73m2) Significant impairment in liver function (Child-Pugh class B or C). Bleeding disorders Hormone-sensitive conditions such as breast cancer, uterine cancer, ovarian cancer, endometriosis, or uterine fibroids. Taking antioxidant medications Performing major surgeries
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **160**
Randomization (investigator's opinion)
Randomized
Randomization description
The method used to generate a random assignment sequence with a guarantee of equal allocation of individuals to two groups is a permutation block that we create using the site www.sealedenvelope.com with block sizes of 2 and 6.The way to do this is to enter the mentioned site, select the RANDOMISATION option from the toolbar at the top of the page, and then press the CREATE A LIST option.Next, we complete the information for each column and click the CREATE LIST button to create the desired list.
Blinding (investigator's opinion)
Double blinded
Blinding description
First, we select a group of patients who are eligible to participate in the study.We implement the allocation concealment method using sealed opaque envelopes with a random sequence obtained from the random allocation step.Then, patients randomly divide into two groups.The first group is the intervention group (receiving treatment or Group A) and the other is the control group (receiving placebo or Group B).At this stage, both the patients and the evaluators (the doctor and the person who analyzes the data) remain unaware of which group is the intervention group and which is the control group.In other words, neither the patients know whether they are receiving the real drug (or treatment) or a placebo, nor do the evaluators know which group is the intervention group and which is the control group.In this study, the drug and placebo with the same shape, taste, and color provide to both groups based on the drug code they receive (A or B).Finally, data from both groups collect and analyze by evaluators, without knowledge of the identities of the groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Vice Chancellor for Research and Technology,Third floor of Ghoreshi building,Next to Hoveyzeh Cinema,Daneshgah Street,Mashhad
City
Masshad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2025-05-10, 1404/02/20
Ethics committee reference number
IR.MUMS.REC.1404.087

Health conditions studied

1

Description of health condition studied
Re-entry ventricular arrhythmia
ICD-10 code
I47.0
ICD-10 code description
Re-entry ventricular arrhythmia

2

Description of health condition studied
Supraventricular tachycardia
ICD-10 code
I47.1
ICD-10 code description
Supraventricular tachycardia

Primary outcomes

1

Description
Ratio of supraventricular and ventricular arrhythmias
Timepoint
At the beginning of the study and 3 months later
Method of measurement
Review of data from implantable cardiac defibrillator devices

Secondary outcomes

1

Description
Shock reduction
Timepoint
Before the start of the study and after 3 months
Method of measurement
Implantable cardiac defibrillator device

2

Description
Antitachycardia Pacing (ATP) depletion
Timepoint
Before the start of the study and after 3 months
Method of measurement
Implantable cardiac defibrillator device

3

Description
Hospitalization rate
Timepoint
Before the start of the study and after 3 months
Method of measurement
Counting the number of days hospitalized

4

Description
Side effects of resveratrol
Timepoint
From the start of the study to 3 months later
Method of measurement
patient monitoring

Intervention groups

1

Description
Intervention group:Resveratrol capsules 250 mg(RAHA Pharmaceutical Co), one capsule daily for three months
Category
Prevention

2

Description
Control group:Placebo capsule similar to resveratrol capsule, manufactured by the Pharmaceutical Laboratory of the Faculty of Pharmacy, Mashhad University of Medical Sciences, one capsule daily for three months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Tayyebi's office
Full name of responsible person
Mohammad Tayebi
Street address
4th Floor - No. 11 , Between Besat 1 and 3 Ave., Intersection of Besat and Mulla Sadra Blvd., Ahmadabad street
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948954
Phone
+98 51 3847 8514
Email
TayyebiM@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Vice Chancellor for Research and Technology,Third floor of Ghoreshi building,Next to Hoveyzeh Cinema,Daneshgah Street,Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 1538 3841
Email
tafaghodiM@mums.ac.ir
Web page address
https://v-research.mums.ac.ir/moavenat/2021-04-06-05-57-55
Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Amirhooshang Mohamadpoor
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
School of Pharmacy, University complex, Vakil Abad boulevard, Azadi square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948954
Phone
+98 51 3180 1592
Email
MohamadpoorAH@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Amirhooshang Mohamadpoor
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
School of Pharmacy, University complex, Vakil Abad boulevard, Azadi square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948954
Phone
+98 51 3180 1592
Email
MohamadpoorAH@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Amirhooshang Mohamadpoor
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
School of Pharmacy, University complex, Vakil Abad boulevard, Azadi square
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Phone
+98 51 3180 1592
Email
MohamadpoorAH@mums.ac.ir

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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals.
When the data will become available and for how long
Access period starts 6 months after results are published.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The use of data is permitted provided the source is cited.

From where data/document is obtainable

Dr. Amir Houshang Mohammadpoor Email: MohamadpoorAH@mums.ac.ir and contact phone: 09153162909

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

Email response within a maximum of one week

Comments