

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Evaluation of the effect of Allopurinol on the frequency of ventricular and supraventricular arrhythmias in patients with an implantable cardioverter-defibrillator

Protocol summary

Study aim

Determining the effect of allopurinol on the frequency of ventricular and supraventricular arrhythmias in patients with implantable cardiac defibrillators.

Design

A clinical trial with a control group, with a parallel group, double-blind, randomized, phase 3 on 134 patients. The site <https://www.sealedenvelope.com/> was used for randomization.

Settings and conduct

This study is conducted on 134 eligible patients in a private doctor's office located in Mashhad. The study is done in a double-blind manner, and the patient, the researcher and the analyst are blind. Medicine and placebo are divided into two groups, A and B, and are given to participating patients randomly in a closed block.

Participants/Inclusion and exclusion criteria

Inclusion criteria include all patients with implantable cardiac defibrillators who visit the doctor's office on an outpatient basis and have informed consent to participate in the clinical trial. The main Exclusion criteria are history of Allopurinol, class I and III antiarrhythmic or anti-inflammatory drugs; moderate to severe kidney dysfunction; significant liver dysfunction.

Intervention groups

In the drug receiving group, patients receive one 300 mg allopurinol tablet daily and in the placebo group, one placebo tablet daily for 3 months.

Main outcome variables

Frequency of ventricular and supraventricular arrhythmias

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120520009801N12**

Registration date: **2024-02-19, 1402/11/30**

Registration timing: **prospective**

Last update: **2024-02-19, 1402/11/30**

Update count: **0**

Registration date

2024-02-19, 1402/11/30

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

2024-04-02, 1403/01/14

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Allopurinol on the frequency of

ventricular and supraventricular arrhythmias in patients with an implantable cardioverter-defibrillator		A and B codes are given to the drug and placebo group and these codes are available to the researcher in the doctor's office. It should be noted that this researcher is fully aware of the types of codes. Also, the drugs are given to him based on the number (A or B) and he is fully aware of which drug is allopurinol or placebo. It should be noted that the placebo sample made by the Pharmaceuticals Laboratory of the Faculty of Pharmacy is completely similar to allopurinol tablets, and therefore patients do not know whether they are in the drug or placebo group.	
Public title	Evaluation of the effect of Allopurinol on the frequency of ventricular and supraventricular arrhythmias	Placebo	Used
Purpose	Prevention	Assignment	Parallel
Inclusion/Exclusion criteria	Inclusion criteria: Age more than 18 years and less than 70 years Having an implantable cardioverter-defibrillator for more than 3 months before starting participation in the clinical trial Obtain informed consent from the patient Exclusion criteria: Taking the drug allopurinol before Moderate to severe kidney dysfunction (GFR < 60 ml/min/1.73m2) Significant impairment of liver function (Child-Pugh class B or C) Previous history of severe skin reactions like Steven Johnson Pregnancy or suspected pregnancy Active inflammation or infection Suffering from autoimmune diseases and malignancies Taking class I and III antiarrhythmic drugs Performing major surgeries Taking any medication with anti-inflammatory effect	Other design features	
Age	From 18 years old	Secondary Ids	empty
Gender	Both	Ethics committees	
Phase	3	1	
Groups that have been masked	- Participant - Care provider - Investigator - Outcome assessor	Ethics committee	
Sample size	Target sample size: 134	Name of ethics committee	Ethics Committee of Mashhad University of Medical Sciences
Randomization (investigator's opinion)	Randomized	Street address	Vice Chancellor for Research and Technology, Third floor of Ghoreschi building, Next to Hoveyze Cinema, Daneshgah Street, Mashhad
Randomization description	The method used to generate a random allocation sequence with the guarantee of equal allocation of people to two groups is a permutation block that is created using the website https://www.sealedenvelope.com/ . With the explanation that 34 blocks of 4 will be randomly generated and patients will be assigned to two study groups based on the sequence obtained from the above blocks. With the explanation that each of the blocks has 4 members and the shape of the blocks is as follows: [AABB], [ABAB], [ABBA], [BABA], [BBAA], [BAAB] Code A corresponds to the intervention group and code B corresponds to the control group. Therefore, 34 quadruple blocks have been randomly created by the site, and patients are assigned to two study groups based on the sequence obtained from the above blocks. Allocation concealment method is by using non-transparent sealed envelopes with random sequence obtained from the random allocation step.	City	Mashhad
Blinding (investigator's opinion)	Double blinded	Province	Razavi Khorasan
Blinding description		Postal code	9138813944
		Approval date	2024-01-02, 1402/10/12
		Ethics committee reference number	IR.MUMS.REC.1402.276
		Health conditions studied	
		1	
		Description of health condition studied	Ventricular arrhythmias
		ICD-10 code	I47.0
		ICD-10 code description	Re-entry ventricular arrhythmia
		2	
		Description of health condition studied	Supraventricular arrhythmia
		ICD-10 code	I47.1
		ICD-10 code description	

Primary outcomes

1

Description

Frequency of ventricular arrhythmias

Timepoint

The beginning of the study and 3 months later

Method of measurement

Examining the data obtained from the implantable cardiac defibrillator device

2

Description

Frequency of supraventricular arrhythmias

Timepoint

The beginning of the study and 3 months later

Method of measurement

Examining the data obtained from the implantable cardiac defibrillator device

Secondary outcomes

1

Description

Uric acid level

Timepoint

Before the intervention and after 3 months

Method of measurement

Biochemistry test of the patient's blood sample

2

Description

blood pressure

Timepoint

Before the intervention and after 3 months

Method of measurement

sphygmomanometer

3

Description

Hospitalization

Timepoint

Before the intervention and after 3 months

Method of measurement

Pulse oximeter device

Intervention groups

1

Description

Intervention group: Allopurinol 300 mg tablets, Hakim Pharmaceuticals, once a day for three months (67 people)

Category

2

Description

Control group: Placebo tablets made by the School of Pharmacy of Mashhad University of Medical Sciences, one daily for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Tayyebi's office

Full name of responsible person

Mohammad Tayyebi

Street address

No. 11, between Besat 1 and 3, Molla Sadra and Besat intersection, Mashhad

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 Ghoreishi building, next to Hoveyze Cinema, University Street, Mashhad

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Postal code

9138813944

Phone

+98 51 3841 1538

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

Amir Hooshang Mohammadpour

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

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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

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 unidentifiable individuals

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

The use of data is unimpeded by mentioning the source.

From where data/document is obtainable

Dr. AmirHoushang Mohamadpour Mail:

mohamadpoorah@mums.ac.ir Phone: 09153162909

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

Reply to email within a maximum of one week

Comments