

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 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

#### Public title

Evaluation of the effect of Allopurinol on the frequency of ventricular and supraventricular arrhythmias

#### Purpose

Prevention

#### 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/1.73m<sup>2</sup>) 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

#### Age

From 18 years old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

#### Sample size

Target sample size: 134

#### Randomization (investigator's opinion)

Randomized

#### 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.

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

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.

#### 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 Hoveyze Cinema, Daneshgah Street, Mashhad

##### City

Mashhad

##### Province

Razavi Khorasan

##### 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

Supraventricular tachycardia

## 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

Prevention

### 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 Ghoreshi building, next to Hoveyzeh Cinema, University Street, Mashhad

##### City

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##### Province

Razavi Khorasan

##### 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**

School of Pharmacy, Mashhad University of Medical Sciences

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**Postal code**

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Amir Hooshang Mohammadpour

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**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Amir Hooshang Mohammadpour

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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**

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**