Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the Effectiveness of 6 mg and 12 mg Adenosine in the Treatment of Paroxysmal Supraventricular Tachycardia

Protocol summary

Study aim
Comparison of the efficacy of 6 mg and 12 mg adenosine in the treatment of supraventricular tachycardia

Design
Clinical trials have two intervention groups, with parallel groups, one-way blind, randomized, and phase 3 on 142 patients. Accidental block method will be used for randomization

Settings and conduct
In the emergency department of Shahid Rajaei Hospital in Karaj, all patients with dysrhythmia are placed in level 1 triage. In the intervention group 1, a dose of 6 mg is used. In the other group, the treatment will be performed at a dose of 12 mg, and if there is no response, a dose of 12 mg and a Valsalva maneuver will be performed. In both groups, if this treatment is not responded to, the patients will continue to be treated according to the patient's condition. (Using shock or other medications)

Participants/Inclusion and exclusion criteria
Entry requirements: The patient must have informed consent to participate in the study. The patient has a supraventricular tachycardia dysrhythmia. Exit conditions:Patient sensitivity to adenosine, grade 2 and 3 AV node blocks, sick sinus syndrome, history of seizures and previous epilepsy

Intervention groups
Patients with a ventricular tachycardia dysrhythmia are placed on first triage level and treated with adenosine.In the intervention 1 group, a dose of 6 mg of adenosine is used first, and in case of non-response, a dose of 12 mg and again, in case of non-response, a dose of 12 mg is used together with Valsalva maneuver and the rhythm of the disc rhythm is recorded.In the intervention 2group, treatments are initially started with a dose of 12 mg adenosine and if the dose is not answered, a dose of 12 mg and a valsalva maneuver will be performed and the rhythm of the disc rhythm will be recorded

Main outcome variables
paroxysmal Supraventricular tachycardia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190929044919N1**
Registration date: **2020-06-16, 1399/03/27**
Registration timing: **retrospective**

Last update: **2020-06-16, 1399/03/27**
Update count: **0**

Registration date
2020-06-16, 1399/03/27

Registrant information

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maryam Fadaeedashti

Name of organization / entity
Alborz University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-20, 1397/12/29

Expected recruitment end date
2020-05-20, 1399/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of 6 mg and 12 mg Adenosine in the Treatment of Paroxysmal Supraventricular Tachycardia

Public title
Evaluation of adenosine efficacy in the treatment of ventricular tachycardia

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The patient should have informed consent to participate in the study The patient has a Paroxysmal Supraventricular Tachycardia The patient's age is in the range of 70-18 years

Exclusion criteria:
The Patient dissatisfaction to participate in the intervention Patient sensitivity to adenosine The patient has first and second degree AV node blocks The patient has sick sinus syndrome The patient has a history of previous seizures and epilepsy

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **142**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization: In this method, four-letter cards are prepared using A-B letters and one card is selected for each patient. If the first letter is card A, the person will be in group one and if it is B, the person will be in group 2.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, while obtaining conscious consent from the patient or their companions, the participants in the intervention are unaware that they are in the intervention group one or two.In this way, the study participant is unaware of which group is involved and receives the initial dose of 12 mg or 6 mg Adenosine

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Alborz University of Medical Sciences

Street address
Safarian Alley,Golshahr,Deputy of research and technology

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Province
Alborz

Postal code
3198764653

Approval date
2019-02-18, 1397/11/29

Ethics committee reference number
IR.ABZUMS.REC.1397.198

Health conditions studied

1

Description of health condition studied
Paroxysmal Supraventricular tachycardia

ICD-10 code
R00

ICD-10 code description
Abnormalities of heart beat

Primary outcomes

1

Description
Heart rhythm

Timepoint
After injecting the final dose of adenosine

Method of measurement
ECG

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: a dose of 6 mg of adenosine is used, and in case of non-response, a dose of 12 mg, and again, in case of non-response, a dose of 12 mg is used along with Valsalva maneuver

Category
Treatment - Drugs

2

Description
Intervention group 2: Treatment is initially started with a dose of 12 mg of adenosine, and if the dose is not met, a dose of 12 mg and a valsalva maneuver will be performed
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaei Hospital
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Alborz 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable