

# 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 2 group, 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

##### Name

maryam Fadaeedashti

##### Name of organization / entity

Alborz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3457 0030

##### Email address

fadaeedashti@abzums.ac.ir

##### 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

##### City

Karaj

##### 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

Maryam Fadaeidashti

##### Street address

Shahid Rajaei Hospital, Shahid Rajaei Ave, Hesarak

##### City

Karaj

##### Province

Alborz

##### Postal code

3197635141

##### Phone

+98 26 3457 0030

##### Email

fadaeidashti@abzums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Alborz University of Medical Sciences

##### Full name of responsible person

Mohammad Noorisepehr

##### Street address

Safarian Alley, Golshahr, Deputy of research and technology

##### City

Karaj

##### Province

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##### Phone

+98 26 3464 3705

##### Email

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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

##### Name of organization / entity

Shahid Rajaei Hospital

##### Full name of responsible person

Maryam Fadaeidashti

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Emergency Medicine

##### Street address

Shahid Rajaei Hospital, Shahid Rajaei Ave, Hesarak

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## Person responsible for scientific inquiries

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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