

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effect of Sedation on the Recurrence Rate of Atrioventricular Nodal Reentrant Tachycardia Ablation

Protocol summary

Summary

We sought to assess the effect of sedation on the recurrence rate of atrioventricular nodal reentrant tachycardia (AVNRT) ablation. To this end, we selected 100 patients diagnosed with AVNRT who referred to our Arrhythmia Clinic. Inclusion criteria: Being diagnosed with AVNRT according to physical examination and ECG and thus being candidates for EPS and ablation; having only one type of arrhythmia; giving consent to treatment with sedatives. Exclusion criteria: Not giving consent to treatment with sedatives; having two types of arrhythmia; having already undergone ablation; having a history of receiving anti-convulsive and psychotropic drugs. We randomly divided the subjects into two groups: the sedation group, which received Midazolam, Fentanyl, and Propofol per Kg (taking necessary precautions), and the control group, which received no sedatives. We, thereafter, compared the recurrence rates of ablation between the two study groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011075124N1**
Registration date: **2011-06-08, 1390/03/18**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-08, 1390/03/18

Registrant information

Name

Ali Eskandari

Name of organization / entity

Shaheed Rajaei Cardiovascular , Medical and

Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2266 3272

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research , Tehran University of Medical Sciences

Expected recruitment start date

2010-02-20, 1388/12/01

Expected recruitment end date

2011-03-20, 1389/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Sedation on the Recurrence Rate of Atrioventricular Nodal Reentrant Tachycardia Ablation

Public title

Effect of Sedation on the Recurrence Rate of Atrioventricular Nodal Reentrant Tachycardia Ablation

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: Being diagnosed with AVNRT according to physical examination and ECG and thus being candidates for EPS and ablation; having only one type of arrhythmia; giving consent to treatment with sedatives. Exclusion criteria: Not giving consent to treatment with sedatives; having two types of arrhythmia; having already undergone ablation; having a history of receiving

anti-convulsive and psychotropic drugs

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences Ethics Committee

Street address

Tehran University of Medical Sciences, Sheikh Fazlollah Noori Highway, Tehran, Iran

City

Tehran

Postal code

Approval date

2010-10-24, 1389/08/02

Ethics committee reference number

896/4

Health conditions studied

1

Description of health condition studied

Atrioventricular nodal reentrant tachycardia

ICD-10 code

I45.8

ICD-10 code description

Other forms of heart disease

Primary outcomes

1

Description

Recurrence of arrhythmia

Timepoint

Three months

Method of measurement

History - physical exam - ECG

Secondary outcomes

1

Description

Timepoint

Method of measurement

Intervention groups

1

Description

The patients were randomly divided into two groups: The sedation group received sedatives, including Midazolam (tranquilizer and soporific) at a dose of 0.03mg/kg every half hour, Fentanyl (opiate analgesic) at a dose of 1µg/kg every half hour, and Propofol (opiate) at a loading dose of 2mg and IV dosage of 100µg/kg adjusted to maintain a Ramsay sedation scale score of 2. All the aforementioned drugs were used only intra-procedurally.

Category

Treatment - Drugs

2

Description

The control group received no drugs for sedation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Rajaei Cardiovascular, Medical and Research Center

Full name of responsible person

Dr. Amir Farjam Fazelifar

Street address

EPS Ward, Shaheed Rajaei Cardiovascular, Medical and Research Center, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran Cardiovascular Research Institute

Full name of responsible person

Dr. Majid Hagho

Street address

Shaheed Rajaei Cardiovascular, Medical and Research Center, Adjacent to Mellat Park, Tehran, Iran

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran Cardiovascular Research Institute

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Shaheed Rajaei Cardiovascular, Medical and Research Center

Full name of responsible person

Mrs. Azam Forghaniyan

Position

Technician of anesthesia

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Person responsible for scientific inquiries

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Shaheed Rajaei Cardiovascular, Medical and Research Center

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Cardiologist- electrophysiologist

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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty