

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Amiodarone and Digoxin in controlling rapid ventricular response atrial fibrillation

Protocol summary

Summary

The purpose of this study is to evaluate the effects of Amiodarone versus Digoxin for control of heart rate in patients with rapid ventricular response atrial fibrillation (AF) referred to emergency room. Patients who are referred to emergency rooms of Imam Hossein and Shohadaye Tajrish hospitals will be the population of this study. The study is a blocked randomized single blind and multicentral, clinical trial. All patients with over 110 beats per minute AF who are referred to emergency room will be included in this study. However, patients with unstable vital signs; under 18 years; without congestive heart failure; presence of hepatic or renal dysfunction; patients who are not willing to participate in this study will be excluded. The total sample size will be 108 patients, including two groups of patients with and without history of atrial fibrillation that each group randomly treated with Amiodarone or Digoxin. The dose of amiodarone is 150 mg over 10 minutes followed by a 50 mg per hour slow infusion for 3 hours then 25 mg per hour for 8 hours. Digoxin is given in an initial slow intravenous dose of 0.5 mg then if needed 0.25 mg in hours 2 and 4 of intervention. The aim is lowering the heart rate below 100 beats per minute. The patients will be monitored during the course of treatment and time of rate control and possible complications (such as hypotension more than 20 mmHg, heart rate less than 60 beats per minute, and other arrhythmia) will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206047449N2**

Registration date: **2012-11-02, 1391/08/12**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-02, 1391/08/12

Registrant information

Name

Majid Shojaee

Name of organization / entity

Shahid Beheshti Medical University

Country

Iran (Islamic Republic of)

Phone

+98 21 7343 2380

Email address

m.shojaee@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti Medical University

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2012-12-21, 1391/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Amiodarone and Digoxin in controlling rapid ventricular response atrial fibrillation

Public title

The effects of Amiodarone for control of heart rate in patients with rapid ventricular response atrial fibrillation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients with over 110 beats per minute Atrial Fibrillation who are referred to emergency room
Exclusion criteria: patients with unstable vital signs who are needed electrical cardioversion; or due to underline diseases such as sepsis, anemia, bleeding, hypovolemia who are needed treatment under 18 or over 80 years; who haven't congestive heart failure; who have received antiarrhythmic agents last 12 hours; who couldn't monitoring 12 hours during the study who are not willing to participate in this study; presence of hepatic or renal dysfunction; atrial fibrillation diagnosis isn't definite in ECG;

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti Medical University, Medical School,
Ethics Committee

Street address

Shahid Beheshti University of Medical Science and
Health Care, Medical School, Koodakyar Deadlock,
Yemen St, Chamran Highway

City

Tehran

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

90-04-08-83

Health conditions studied

1

Description of health condition studied

Atrial fibrillation

ICD-10 code

I48

ICD-10 code description

Atrial fibrillation and flutter

Primary outcomes

1

Description

Heart rate

Timepoint

Before the intervention, and during 12 hours of the
intervention and one week after intervention

Method of measurement

Heart rate based on ECG and cardiac monitoring

Secondary outcomes

1

Description

Time to response

Timepoint

During 12 hours of intervention

Method of measurement

Heart rate based on ECG and cardiac monitoring

2

Description

Decrease in blood pressure more than 20 mmHg

Timepoint

During 12 hours of intervention

Method of measurement

Standard sphygmomanometer 2 times with 2 persons

3

Description

Decrease in heart rate less than 60 beats per minute

Timepoint

Every 1 hour during 12 hours of intervention

Method of measurement

Heart rate based on ECG and cardiac monitoring

4

Description

Occurrence of other arrhythmias

Timepoint

During 12 hours of intervention

Method of measurement

Based on ECG and cardiac monitoring

Intervention groups

1

Description

for intervention: Intravenous Amiodarone 150 mg over 10 minutes followed by a 50 mg per hour slow infusion for 3 hours then 25 mg per hour for 8 hours.

Category

Treatment - Drugs

2

Description

For control: Digoxin is given in an initial slow intravenous dose of 0.5 mg then if needed 0.25 mg in hours 2 and 4 of intervention.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam hossein Medical & Educational Center

Full name of responsible person

Dr Majid Shojaee

Street address

Emam hossein Medical & Educational Center, Shahid Madani st.

City

Tehran

2

Recruitment center

Name of recruitment center

Shohadaye Tajrish Medical & Educational Center

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Miss Tadaion

Street address

Shahid Beheshti University of Medical Science and Health Care, Koodakyar Deadlock, Yemen St, Chamran Highway

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

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

Shahid Beheshti Medical University

Full name of responsible person

Dr Majid Shojaee

Position

Assistant Professor of Emergency Medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

Contact

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Full name of responsible person

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Position

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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