

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Pre-hospital administration of Amiodarone for reducing the short-time mortality of AICS.

Protocol summary

Summary

The objective of this trial is to investigate the effect of administration of Amiodarone on the mortality rate of arrhythmia following acute coronary syndrome. The main inclusion criteria is having acute coronary syndrome sign and symptoms. A total of 2400 patients whom transferred to the hospitals by EMS are recruited in the trial and randomly assigned to receive Amiodarone or distilled water before hospital admission. EKG findings and cardiac enzymes will be investigated on arrival to the hospital on the 7th and 30th day after beginning of symptoms.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138905064357N2**
Registration date: **2010-09-30, 1389/07/08**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-09-30, 1389/07/08

Registrant information

Name

Ali Bidari

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences, Iranian Emergency and Disaster Management Center

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-04-20, 1390/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pre-hospital administration of Amiodarone for reducing the short-time mortality of AICS.

Public title

Pre-hospital administration of Amiodarone for reducing the short-time mortality of AICS.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Presence of Acute Coronary Syndrome criteria referred to hospitals with EMS with the following conditions: diffuse precordial or substernal pain with at least 20 min duration and lasts until patient visits by EMS, no other significant diagnosis for present chest pain, age more than 45 years old in men and more than 50 years old in women, Systolic Blood Pressure 100mm/Hg or higher, Pulse Rate equal to 60 or more, no history of drug sensitivity to Amiodarone

Age

From **45 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 2400

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Hemmat highway

City

Tehran

Postal code

Approval date

2010-09-12, 1389/06/21

Ethics committee reference number

893/13

Health conditions studied

1

Description of health condition studied

Acute coronary syndrome

ICD-10 code

I24.9

ICD-10 code description

Acute Ischaemic Heart Disease

Primary outcomes

1

Description

incidence of arrhythmia

Timepoint

on arrival to hospital

Method of measurement

EKG analysis in hospital

Secondary outcomes

1

Description

Mortality rate

Timepoint

a week and a month later

Method of measurement

Death rate during a month after the intervention

Intervention groups

1

Description

Amiodarone, 100mg, IV, in 10 minutes or more before admission to the hospital

Category

Treatment - Drugs

2

Description

Distilled water as placebo, with the same volume and shape as amiodarone, in 10 minutes or more, before admission to the hospital

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Emergency and Disaster Management Center

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian Emergency and Disaster Management Center

Full name of responsible person

Dr Nader Tavakoli

Street address

Jomhuri ave.Iranian emergency research center

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iranian Emergency and Disaster Management Center

Proportion provided by this source

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

2

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr Maziar Morady
Street address
Hemmat highway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
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
Iran University Of Medical Sciences
Full name of responsible person
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Person responsible for scientific inquiries

Contact

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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