Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Sep 2026

Randomized clinical trial of the comparison of splinting/non splinting in prevention of superficial phlebitis following Amiodarone Injection in patients with Cardiac Arrhythmia

Protocol summary

Summary

Objectives: Reducing the incidence of phlebitis and its complications Design: The study population will consist of 60 patients admitted to the CCU of Tehran Heart Center Hospital due to atrial fibrillation or ventricular tachycardia, for which Amiodarone is administered. The patients, who are not blinded and provide informed consent, will be randomly divided into 2 groups (with and without splints) (clinical trial, phase I). Method: After the administration of Amiodarone due to atrial fibrillation or ventricular tachycardia, the patients will be randomly allocated to one of the 2 groups. Hand splinting was performed for case group by a trained nurse. Inclusion criteria: Age between 18 and 65 years, Amiodarone administration for atrial fibrillation or ventricular tachycardia, Starting dose of Amiodarone administration at CCU, Informed consent of the patient regarding the use of the splint, no history of cancer and chemotherapy, absence of deep vein thrombosis, no history of renal failure and dialysis, and non-consumption of broad-spectrum antibiotics and steroids Interventions: Hand splinting in case group by a trained nurse who has been well-trained in the field of splinting in orthopedic emergencies through the academic training courses Main outcome: Phlebitis and infection at the site of phlebitis

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061622768N1**
Registration date: **2016-02-24, 1394/12/05**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-02-24, 1394/12/05

Registrant information

Name
Saeed Sadeghian
Name of organization / entity
Tehran University of Medical Sciences, Tehran Heart Center Hospital
Country
Iran (Islamic Republic of)
Phone
+98 21 8802 9256
Email address
ssadeghian@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2016-03-05, 1394/12/15

Expected recruitment end date

2016-07-05, 1395/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized clinical trial of the comparison of splinting/non splinting in prevention of superficial phlebitis following Amiodarone Injection in patients with Cardiac Arrhythmia

Public title

Effect of Hand Splinting on the Prevention of

Inflammation following Amiodarone Injection in Patients with Cardiac Arrhythmia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1- Age between 18 and 65 years 2- Amiodarone administration for atrial fibrillation or ventricular tachycardia 3- Starting dose of Amiodarone administration at CCU 4- Informed consent of the patient regarding the use of the splint. In case of the patient's incapacity, informed consent will be obtained from the patient's first-degree relatives (e.g., parents). The patients will be reassured that their treatment course will not be affected by non-participation in the study. Exclusion criteria: 1- History of cancer and chemotherapy, deep vein thrombosis, renal failure and dialysis, consumption of broad-spectrum antibiotics and steroids 2- Removal of the splint in consequence of the patient's agitation 3- Refusal to give consent for participation in the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

N/A

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 and Health Services Ethics committee

Street address

4th Floor, Number 23,16th Azar St., Keshavarz Blvd.,Tehran

City

Tehran

Postal code

1417614411

Approval date

2015-10-13, 1394/07/21

Ethics committee reference number

IR.tums.REC.1394.949

Health conditions studied

1

Description of health condition studied

Phlebitis

ICD-10 code

180.8

ICD-10 code description

Phlebitis and phlebitis of other sites

Primary outcomes

1

Description

Pain

Timepoint

Checking the injection site for 24 hours, starting from 1 hour after the injection of Amiodarone

Method of measurement

Self-report of pain at the injection site

2

Description

Redness

Timepoint

Checking the injection site for 24 hours, starting from 1 hour after the injection of Amiodarone

Method of measurement

Checking the injection site for redness at 1 hour intervals

3

Description

Inflammation

Timepoint

Checking the injection site for 24 hours, starting from 1 hour after the injection of Amiodarone

Method of measurement

Checking the injection site for inflammation

Secondary outcomes

1

Description

Injection site infection

Timepoint

Observation and checking of the injection site at 1 hour intervals until the resolution of the signs of phlebitis

Method of measurement

The observation and checking of injection site

Intervention groups

1

Description
Intervention 1: Splinting of the Amiodarone injection site with 2types of splints (designed by Kalay-e Pezeshki-e Ghalb Company): one for of the wrist and the other for the elbow
Category
Prevention

2

Description
2: No splinting at the site of Amiodarone injection
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Heart Center Hospital
Full name of responsible person
Saeed Sadeghian, MD
Street address
1st Floor, Cardiovascular Research Department of Tehran Heart Center Hospital, Jalal-E-Al-E-Ahmad and North Karegar Cross, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences, Vice Chancellor For Research
Full name of responsible person
Masoud Yunesian, MD, PhD
Street address
Vice Chancellor For Research, 6th Floor, Central Building of Tehran University of Medical Sciences, Ghods St., Keshavarz Blvd., Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences, Vice Chancellor For Research
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
Tehran Heart Center Hospital
Full name of responsible person
Farah Ayatollah Zadeh Esfahani
Position
BSc of Nursing
Other areas of specialty/work
Street address
4th Floor, Cardiovascular Research Department of Tehran Heart Center, Jalal-E- Al-E- Ahmad and North Karegar Cross, Tehran
City
Tehran
Postal code
1411713138
Phone
+98 21 8802 9708
Fax
+98 21 8802 9731
Email
rose8a2001@yahoo.com bitadavoudi@yahoo.com pashang_mina@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
saeed sadeghian, MD
Position
MD and higher, Associate Professor of Cardiovascular Disease, Tehran University of Medical Sciences
Other areas of specialty/work
Street address
1st Floor, Cardiovascular Research Department of Tehran Heart Center Hospital, Jalal-E- Al-E- Ahmad and North Karegar Cross, Tehran
City
Tehran
Postal code
1411713138
Phone
+98 21 8802 9256
Fax
+98 21 8802 9731
Email
rose8a2001@yahoo.com bitadavoudi@yahoo.com pashang_mina@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Farah Ayatollah Zadeh Esfahani

Position
Research Nurse

Other areas of specialty/work

Street address
4th Floor, Cardiovascular Research Department of Tehran Heart Center Hospital, Jalal-E-Al-E- Ahmad and North Karegar Cross, Tehran

City
Tehran

Postal code
1411713138

Phone
+98 21 8802 9708

Fax
+98 21 8802 9731

Email
rose8a2001@yahoo.com

Web page address

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