Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of chamomile ointment on iIncidence of phlebitis caused by intravenous amiodarone in cardiac care unit in selected Qazvin's hospitals: 2013

Protocol summary

Summary

This study aimed to investigate the effect of chamomile ointment on the incidence of phlebitis caused by amiodaron infusion through a peripheral vein. In a double-blind clinical trial, 42 patients will be treated with amiodarone for 24 hours in one of the two groups are based on random selection: Placebo and treatment groups. After random selection of chamomile or placebo ointment is applied in IV cannula place every 8 hours for 3 days and during this period the incidence of phlebitis checked with phlebitis scale. Amiodarone will be injected from a single IV injection the patient did not receive any medication through that cannula.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042017361N1**
Registration date: **2014-06-02, 1393/03/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-06-02, 1393/03/12

Registrant information

Name

Marjan Nassiri-Asl

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Qaznin University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of chamomile ointment on iIncidence of phlebitis caused by intravenous amiodarone in cardiac care unit in selected Qazvin's hospitals: 2013

Public title

Effect of chamomile ointment on incidence of phlebitis caused by amiodarone

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Treated with amiodarone for 24 hours; Not allergic to chamomile ointment; Not diabetic; Age 18 to 75 years Exclusion criteria: Chamomile Ointment sensitivity expressed by patients before study entry or during the study period, based on the research team ;Scar, surgical scar or deformity that prevented IV cannula insertion of the upper limbs; Peripheral vascular disease; Use of chemotherapy medication; To prescribe oral or injectable anti-inflammatory drugs during the study period; The patient does not consent to continue to participate in the study; IV cannula exit; The drug

discontinue before 24 hours; Diagnosis of diabetes after study entry; Cancer history; Patient expired; Patient discharge

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

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
Qazvin University of Medical Sciences

Street address
Deputy of Research, Bahonar Blvd, Qazvin University of Medical Scieces

City
Qazvin

Postal code

Approval date
2014-03-02, 1392/12/11

Ethics committee reference number
8486/20/28

Health conditions studied

1

Description of health condition studied
Phlebitis

ICD-10 code
I80

ICD-10 code description
Phlebitis and thrombophlebitis

Primary outcomes

1

Description
Phlebitis

Timepoint
Fisrt, Second and third 24 h

Method of measurement
Check list for phelebitis VIP (score 0-4)

Secondary outcomes

empty

Intervention groups

1

Description
This study is randomized double blind clinical trials. Drug group: The patients with ventricular or supraventricular arrhythmias that will admitted in the cardiac care unit will be treated with amiodarone for 24 h. Infusion of amiodarone with 150 mg over 10 min and with 6 mg/min for 6 h and 0.5 mg/min for 18 h will be continued. Chamomile ointment as a fingertip will apply ten cm above the IV injection route of amiodarone, as the skin is completely covered with ointment and it will be repeated every 8 hours for three days. During this time, the location will be checked of phlebitis, pain, swelling, redness by researcher every 8 hours and if needed.

Category
Prevention

2

Description
Control group: The patients with ventricular or supraventricular arrhythmias that will admitted in the cardiac care unit will be treated with amiodarone for 24 h. Infusion of amiodarone with 150 mg over 10 min and with 6 mg/min for 6 h and 0.5 mg/minute for 18 h will be continued. Placebo ointment as a fingertip will apply ten cm above the IV injection route of amiodarone, as the skin is completely covered with ointment and it will be repeated every 8 hours for three days. During this time, the location will be checked of phlebitis, pain, swelling, redness by researcher every 8 hours and if needed.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
BuAli Hospital

Full name of responsible person
Maryam Sharifi

Street address
BuAli Hospital, BuAli Ave

City
Qazvin

2

Recruitment center
Name of recruitment center
Velayat Hospital
Full name of responsible person
Maryam Sharifi
Street address
Velayat Hospital, Minodar Ave
City
Qazvin

3

Recruitment center
Name of recruitment center
Razi Hospital
Full name of responsible person
Maryam Sharifi
Street address
Razi Hospital, Daneshgah Ave
City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr.Saeed Asefzadeh
Street address
Qazvin University of Medical Sciences, Bahonar Blvd
City
Qazvin
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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

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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