

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Effect of chamomile ointment on incidence 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 amiodarone 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)

Phone

+98 28 3333 6001

Email address

mnassiriasl@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Qazvin 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 incidence 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 Sciences

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

First, Second and third 24 h

Method of measurement

Check list for phlebitis 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

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr.Marjan Nassiri-Asl

Position

Supervisor/Ph.D Pharmacology

Other areas of specialty/work**Street address**

Qazvin University of Medical Sciences, Bahonar Blvd

City

Qazvin

Postal code**Phone**

+98 28 3333 6001

Fax**Email**

mnassiriasl@qums.ac.ir,

marjannassiriaslm@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr.Marjan nassiri-Asl

Position

Supervisor/Ph.D Pharmacology

Other areas of specialty/work**Street address**

Qazvin University of Medical Sciences, Bahonar Blvd

City

Qazvin

Postal code**Phone**

+98 28 3333 6001

Fax**Email**

mnassiriasl@qums.ac.ir,

marjannassiriaslm@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Marjan Nassiri-Asl

Position

Faculty Staff/Ph.D Pharmacology

Other areas of specialty/work**Street address**

Qazvin University of Medical Sciences, Bahonar Blvd

City

Qazvin

Postal code

341197-5981

Phone

+98 28 3333 6001

Fax

+98 28 3332 4970

Email

mnassiriasl@qums.ac.ir,

marjannassiriaslm@gmail.com

Web page address

www.qums.ac.ir

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