

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effects of sesame oil on prevention of phlebitis caused by peripheral vein infusion of amiodarone in cardiac patient.

Protocol summary

Summary

Objective; this study is performed to assess the effect of sesame oil on prevention of phlebitis caused by peripheral vein infusion of Amiodarone. 2. Design; this study is a controlled randomized double blind clinical trial. 3. Setting and conduct; thirty six eligible patients will be randomly placed in experimental and control groups. At first demographic and clinical characteristics of the patients will be recorded in questionnaire. 4. Inclusion major criteria; being over 18 years old, don't have any history of allergy to the sesame seeds, using of the upper extremity for intravenously catheterization. Exclusion criteria; having autoimmunity disease, using analgesics and narcotics to mitigate pain continuously, using drugs or herbal oil to prevent phlebitis during the study, Bradycardia and death of the patient. 5. Intervention; thirty six cardiac patients that receive peripheral intravenous Amiodarone will be randomly divided into two groups. The phlebitis will be measured with Visual infusion phlebitis Scale (VIP) in two groups. In the experimental group, at first the catheterization is performed observing aseptic conditions. Then before the injection of first dose of Amiodarone, as 5 drops of pure sesame oil (produced by Barij Essence, Kashan, Iran) will be rubbed around 10 cm around the area of intravenous Amiodarone injection are applied. And then Amiodarone infusion start and sesame oil will be rubbed every 6 hours during 24 hours (4 times) in the area. In control group will be rubbed liquid paraffin (produced by MERK, Germany, cod: 1.07160) as placebo. The amount and method of using liquid paraffin is exactly same as using of sesame oil in the experimental group. Phlebitis will be measure consecutive 30 hours in each group. 6 main outcome measures variables; Effects of sesame oil on prevention of phlebitis caused by peripheral vein infusion of Amiodarone.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308127494N7**

Registration date: **2014-03-11, 1392/12/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-11, 1392/12/20

Registrant information

Name

Masoumeh Bagheri Nesami

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mazandaran University of Medical Science, Moalem square , Moalem street ,Sari.

Expected recruitment start date

2013-12-31, 1392/10/10

Expected recruitment end date

2014-03-30, 1393/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of sesame oil on prevention of phlebitis caused by peripheral vein infusion of amiodarone in cardiac patient.

Public title

Effects of sesame oil on prevention of phlebitis caused by peripheral vein infusion of amiodarone.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion major criteria; being over 18 years old; don't have any history of allergy to the sesame seeds; using of the upper extremity for intravenously catheterization. Exclusion major criteria; having autoimmunity disease; using analgesics and narcotics to mitigate the pain continuously; using drugs or herbal oil to prevent phlebitis during the study; Bradicardia and death of the patient.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **36**

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**

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Vice chancellor for research of Mazandaran University of Medical Science, Moalem square , Moalem street ,Sari.

City

Sari

Postal code

4758173676

Approval date

2014-03-05, 1392/12/14

Ethics committee reference number

92-570

Health conditions studied**1****Description of health condition studied**

phlebitis

ICD-10 code

I80.0

ICD-10 code description

Phlebitis and thrombophlebitis of other sites

Primary outcomes**1****Description**

phlebitis

Timepoint

Before and during the study-Phlebitis will be measure consecutive 30 hours in each group

Method of measurement

visual infusion phlebitis scale

Secondary outcomes**1****Description**

Prevention of phlebitis

Timepoint

after intervention, Phlebitis will be measure consecutive 30 hours in each group

Method of measurement

Visual infusion phlebitis Scale (VIP)

Intervention groups**1****Description**

Intervention1: In the experimental group, at first the catheterization is performed observing aseptic conditions. Then before the injection of first dose of Amiodarone, as 5 drops of pure sesame oil (produced by Barij Essence, Kashan, Iran) will be rubbed around 10 cm around the area of intravenous Amiodarone injection are applied. And then Amiodarone infusion start and sesame oil will be rubbed every 6 hours during 24 hours (4 times) in the area. Essence, Kashan, Iran) as 5 drops of around 10 cm in the path where the intravenous amiodarone injection are applied. And then amiodarone infusion start and sesame oil is applied every 6 hours to 24 hours (4 times) in the area

Category

Treatment - Drugs

2

Description

Intervention2: In control group will be rubbed liquid paraffin (produced by MERK.Germany.cod:1.07160) as placebo. The amount and method of using liquid paraffinis as exactly same as using of sesame oil inthe experimental group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yahya Nejad Babol Hospital

Full name of responsible person

Seyedeh Zahra Hashemi Karoie

Street address

Yahya Nejad Hospital. martyr Mostafa Khomeini, the Farhang Cross, Babol.

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mazandaran University of Medical Science

Full name of responsible person

Dr Ahmad Ali Enayeti

Street address

Vice chancellor for research of Mazandaran University of Medical Science, Moalem square , Moalem street ,Sari.

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Mazandaran University of Medical Science

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

Mazandaran University of Medical Science

Full name of responsible person

Dr Mohamad Ali Heydari Gorji

Position

Phd- faculty

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Masoumeh Bagheri Nesami

Position

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Other areas of specialty/work

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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