

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Investigating Comparison of topical Rosemary and Nitroglycerine ointment on incidence time of Phlebitis due to peripheral catheterization in children

Protocol summary

Study aim

Comparison of topical effect of rosemary ointment with nitroglycerin ointment At the time of phlebitis due to peripheral catheterization in children.

Design

Clinical practice with control group, double blind, randomized

Settings and conduct

The sample size is 144 samples from Shahid Sadoughi Hospital in Yazd . Patients are randomly divided into two intervention groups and one control group. In the intervention groups, after fixing the catheter rosemary or nitroglycerin ointment is applied in the area below the catheter site and in the control group Ocerin ointment it is used once a day for up to three days. The phlebitis check list will be recorded according to the VIPAS criterion.

Participants/Inclusion and exclusion criteria

inclusion criteria: Children hospitalized in Shahid Sadoughi Hospital Having an age of 1 to 12 years Failure to receive chemotherapy drugs Lack of underlying diseases such as diabetes and autoimmune diseases and skin infections Do not use steroids, immunosuppressive drugs and anticoagulants No previous phlebitis at the site of angiocatheter placement Lack of skin and peripheral vascular disease Lack of sensitivity to nitroglycerin ointment or Rosemary ointment

Intervention groups

In a group of rosemary ointments (1 cm in size), 0.5 cc of ointment is applied once a day for three days after Putting angiocatheter at the site below the angiocatheter entry site, followed by sterile gauze and It is covered and fixed with anti-allergy glue and fixed with a splint. In the other group, 2% nitroglycerin ointment is used in the same way with a dose of 2.5 mg (equivalent to 10 units of insulin syringe) and used in the same way in the control group of ucerine ointment.

Main outcome variables

phlebitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131228015965N19**

Registration date: **2020-06-17, 1399/03/28**

Registration timing: **prospective**

Last update: **2020-06-17, 1399/03/28**

Update count: **0**

Registration date

2020-06-17, 1399/03/28

Registrant information

Name

Majid Kazemi

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-20, 1399/03/31

Expected recruitment end date

2020-10-20, 1399/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating Comparison of topical Rosemary and Nitroglycerine ointment on incidence time of Phlebitis due to peripheral catheterization in children

Public title

Investigating Comparison of topical Rosemary and Nitroglycerine ointment on incidence time of Phlebitis due to peripheral catheterization

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Children hospitalized in Shahid Sadoughi Hospital Having an age of 1 to 12 years Parental satisfaction for the child's participation in the study Failure to receive chemotherapy drugs Lack of underlying diseases such as diabetes and autoimmune diseases and skin infections Do not use steroids, immunosuppressive drugs and anticoagulants Need a catheter for at least 72 hours

Exclusion criteria:

previous phlebitis at the site of angiocatheter placement skin and peripheral vascular disease Sensitivity to nitroglycerin or Rosemary ointment

AgeFrom **1 year** old to **12 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor

Sample sizeTarget sample size: **144****Randomization (investigator's opinion)**

Randomized

Randomization description

Accidental block randomization based on age and sex The 6-person block includes two in the Rosemary group, two in the nitroglycerin group, and two in the control group. For random sequencing in each block, Roll a dice is used in such a way that the numbers 1 and 2 for the first block (Rosemary), 3 and 4 for the second block (nitroglycerin), 5 and 6 for the third block (control) are considered.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. That Participants are not aware of the type of material used in the intervention. Also person evaluating the phlebitis that she only examines the location of the angiocatheter for sign of phlebitis would be blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research ethics committee of Rafsanjan University of Medical Sciences

Street address

Rafsanjan University of Medical Sciences, Imam Ali Boulevard, Rafsanjan

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Rafsanjan

Province

Kerman

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7717932777

Approval date

2020-02-18, 1398/11/29

Ethics committee reference number

IR.RUMS.REC.1398.194

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 score based on Visual Infusion Phlebitis Assessment Scale criteria

Timepoint

Every 12 hours to 72 hours

Method of measurement

Visual Infusion Phlebitis Assessment Scale Grade 1 has none of the typical symptoms of phlebitis such as pain, rash, and edema. Only catheter observation is recommended. Grade 2 describes the early symptoms of phlebitis, such as pain upon palpation and a rash less than 2.5 cm in diameter around the catheter site. Visual Infusion Phlebitis Assessment Scale suggests catheter replacement. Grade 3 phlebitis refers to mid-level disease: IV site rashes are between 2.5 and 5 cm, and palpation of the IV site reveals pain and rigidity.

Treatment should be considered after catheter replacement and doctor notification. Grade 4 phlebitis is advanced phlebitis or the onset of thrombophlebitis. At this level, there is a rash larger than 5 cm around the IV site and pain and rigidity upon palpation. Visual Infusion Phlebitis Assessment Scale recommends catheter replacement, doctor consultation, and consideration of treatment. Finally, grade 5 phlebitis describes advanced thrombophlebitis. This grade includes grade 4 symptoms as well as purulent drainage. Recommendations include treatment consideration after catheter replacement and doctor notification.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1 :Intervention group receiving Rosemary ointment, produced by Gol Daroo Isfahan Company, Product Ingredients: Every 30 grams of ointment containing 2.4 grams of rosemary essential oil, 2.1 grams of camphor, 1/2 mg of menthol 0.5 cc of ointment once a day for three days after Putting angiocatheter at the site below the angiocatheter entry site and Every 12 hours, the symptoms of phlebitis are assessed by the VIPAS.

Category

Treatment - Drugs

2

Description

Intervention group 2 :receiving Nitroglycerin ointment CHEM A-ELEKTROMET [Poland] used 2% nitroglycerin ointment at a dose of 2.5 mg (equivalent to 10 units of insulin syringes) once a day for three days after Putting angiocatheter at the site below the angiocatheter entry site and Every 12 hours, the symptoms of phlebitis are assessed by the VIPAS.

Category

Treatment - Drugs

3

Description

Control group:receiving ucerin , 0.5 cc of ucerin once a day for three days after Putting angiocatheter at the site below the angiocatheter entry site and Every 12 hours, the symptoms of phlebitis are assessed by the VIPAS.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital

Full name of responsible person

Dr. Majid Kazemi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rafsanjan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Majid Kazemi

Position

associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Latest degree

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Other areas of specialty/work

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Phone

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available