# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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 fromShahid 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

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Iran (Islamic Republic of)

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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
**Age**
From **1 year** old to **12 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**

- Care provider
- Investigator
- Outcome assessor

**Sample size**
Target 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 phelebitis 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
**City**
Rafsanjan
**Province**
Kerman
**Postal code**
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**

Shahid Sadoughi Hospital

**Full name of responsible person**

Dr. Majid Kazemi

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Shahid Sadoughi Hospital Ibn Sina Boulevard Shahid Ghandi Boulevard safaie Yazd

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## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**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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## Person responsible for updating data

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## 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