

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of the effect of Rosemary ointment and Eucerine ointment on the incidence, severity of phlebitis and peripheral vascular catheter survival time in hospitalized Neonates

Protocol summary

Study aim

Determining the effect of Rosemary ointment and Eucerine ointment on the incidence, severity of phlebitis and peripheral vascular catheter survival time in hospitalized Neonates

Design

Clinical trial with a control group and parallel groups, triple blinded, randomized

Settings and conduct

This research will be conducted in the neonatal and NICU wards of Ganjavian Hospital in Dezful. The study is triple blind (statistical counselor, patient, researcher and colleagues) in which secretary of the ward (aware of the type intervention) who is not a member of the research team, assigns the baby code A (intervention) or code B (control) at the time of neonatal admitted. Then Rosemary ointment or Eucerine, which has already been placed in similar tubes with labels A and B in collaboration with the pharmacy, is given to research colleagues (fixed IV line) from the pharmacy shelf.

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 1 to 30 days, intravenous access for at least 72 hours. Non-inclusion criteria: perinatal and peripheral vascular disease, usage of steroidal drugs, heparin, nitroglycerin.

Intervention groups

Intervention group: from the time of fixing the IV canulla, 0.5 CC of the Rosemary ointment every 24 hours up will be used until 72 hours. Control group: Since fixing the IV canulla, 0.5 CC Eucerine ointment (placebo) every 24 hours will be used up to 72 hours in the distal part of the IV canulla.

Main outcome variables

Incidence and severity of Phlebitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170607034381N5**

Registration date: **2020-06-10, 1399/03/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-10, 1399/03/21**

Update count: **0**

Registration date

2020-06-10, 1399/03/21

Registrant information

Name

Ferdos Pelarak

Name of organization / entity

Dezful Azad University

Country

Iran (Islamic Republic of)

Phone

+98 916 941 7091

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-10, 1398/12/20

Expected recruitment end date

2020-08-10, 1399/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Comparison of the effect of Rosemary ointment and Eucerine ointment on the incidence, severity of phlebitis and peripheral vascular catheter survival time in hospitalized Neonates
Public title	The effect of Rosemary ointment on phlebitis and survival time of IV canulla
Purpose	Prevention
Inclusion/Exclusion criteria	
Inclusion criteria:	age 1 to 30 day intravenous access for at least 72 hours
Exclusion criteria:	Suffering from skin and peripheral vascular diseases Taking steroid medications Heparin injection Nitro glycerin (injectable, topical)
Age	From 1 day old to 30 days old
Gender	Both
Phase	2-3
Groups that have been masked	• Participant • Investigator • Outcome assessor • Data analyser
Sample size	Target sample size: 64
Randomization (investigator's opinion)	Randomized
Randomization description	The strata are based on the hospital ward, age category, and sex of the neonate using the stratified random allocation method (8 classes). Inside each class, to assign neonates to two groups, Permuted block randomization methods and the table of random numbers are used (1 to 1 allocation).
Blinding (investigator's opinion)	Triple blinded
Blinding description	The study is triple blind (statistical counselor, patient, researcher and colleagues) in which secretary of the ward (aware of the type intervention) who is not a member of the research team, assigns the baby code A (intervention) or code B (control) at the time of neonatal admitted. Then Rosemary ointment or Eucerrine, which has already been placed in similar tubes with labels A and B in collaboration with the pharmacy, is given to research colleagues (fixed IV line) from the pharmacy shelf.
Placebo	Used
Assignment	Parallel
Other design features	

Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Khorram-Abad University of Medical Sciences
Street address	Khorramabad University of Medical Sciences; 5th km of Khorramabad (Kamalvand)
City	Khorram-Abad
Province	Lorestan
Postal code	6813833946
Approval date	2020-03-02, 1398/12/12
Ethics committee reference number	IR.LUMS.REC.1398.263

Health conditions studied

<u>1</u>	
Description of health condition studied	Phlebitis
ICD-10 code	I80
ICD-10 code description	Phlebitis and thrombophlebitis

Primary outcomes

<u>1</u>	
Description	Incidence of Phlebitis
Timepoint	24,48,72 hourse after catheter placement
Method of measurement	Phlebitis scale

Secondary outcomes

<u>1</u>	
Description	Severity of phlebitis
Timepoint	24,48,72 hourse after catheter placement
Method of measurement	Phlebitis scale

Intervention groups

1

Description

Intervention group: The rosemary ointment made by Gol Daroo Company is rubbed in the distal part of the IV canulla in an area of 1 cm squared and will be covered with a sterile coating (IV canulla adhesive). It is replaced every 24 hours and checked and registered for phlebitis up to 72 hours.

Category

Prevention

2

Description

Control group: The Eucerine ointment as a placebo made by Gol Daroo Company is rubbed in the distal part of the IV canulla in an area of 1 cm squared and will be covered with a sterile coating (IV canulla adhesive). It is replaced every 24 hours and checked and registered for phlebitis up to 72 hours

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Ganjavian Hospital

Full name of responsible person

Azadeh Nasrollahnejad

Street address

At the beginning of Dezful-Andimeshk road

City

Dezful

Province

Khouzestan

Postal code

64611-33549

Phone

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Email

a.nasrollahnejad1403@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr.Kobra Karami

Street address

Khorramabad University of Medical Sciences; 5th km of Khorramabad (Kamalvand)

City

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Lorestan

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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

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr.Kobra Karami

Position

Associate Professor of Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr.Kobra Karami

Position

Associate Professor of Nursing

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

Khoram-Abad University of Medical Sciences

Full name of responsible person

Azadeh Nasrollah.nejad

Position

MSc Student of Pediatric Nursing

Latest degree

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Other areas of specialty/work

Nursery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

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