Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effectiveness of Chlorhexidine 2% and Betadine-Alcohol on Phlebitis after Peripheral Vascular Catheterization in Preterm Neonates

Protocol summary

Study aim

Comparing the effects of Chlorhexidine 2% and Betadine-Alcohol on phlebitis after peripheral vascular catheterization in preterm neonates

Design

The clinical trial consisted of 140 samples(Each group n= 70) in two intervention groups, with parallel groups, single blinded, randomized using block randomization method

Settings and conduct

Premature infants admitted to the neonatal intensive care unit of Kamali hospital in Karaj who need catheterization of the peripheral vein for the first time, will enter the study in an accessible way and then will be randomly divided into two groups.In group 1, the catheterization site is disinfected with chlorhexidine gluconate 2% solution and in group 2, betadine 10% and alcohol 70% are used to disinfect the catheterization site in two stages

Participants/Inclusion and exclusion criteria

Inclusion criterion: Premature neonates who need peripheral vascular catheterization for the first time. Exclusion criteria: Signs of inflammation at the selected site of catheter insertion; symptoms of bacteremia; symptoms of septicemia such as fever greater than 38. C, leukocytosis, tachycardia and respiratory rate greater than 60

Intervention groups

Intervention group 1: The skin of the catheterization area is disinfected with chlorhexidine gluconate 2% solution. Intervention group 2: The skin of the catheterization area is first disinfected with Iodine 10%, then allowed to dry with Iodine and then discharged with alcohol 70% and when it dry , the catheterization will be done

Main outcome variables

Phlebitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170620034653N5**
Registration date: **2020-05-16, 1399/02/27**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-16, 1399/02/27**
Update count: **0**

Registration date

2020-05-16, 1399/02/27

Registrant information

Name

Zahra Tayebi Myaneh

Name of organization / entity

Qazvin University of medical science

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the Effectiveness of Chlorhexidine 2% and Betadine-Alcohol on Phlebitis after Peripheral Vascular Catheterization in Preterm Neonates

Public title
Comparison of the Effectiveness of Chlorhexidine 2% and Betadine-Alcohol on Phlebitis

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Premature neonate For the first time in the intensive care unit, the neonate needs peripheral vein catheterization

Exclusion criteria:
Symptoms of septicemia in neonate The presence of bacteremia in the neonate (positive primary CRP or positive blood culture) Symptoms of inflammation in the area used for venous catheterization

Age
From **224 days** old to **259 days** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation by blocks of size 4

Blinding (investigator's opinion)
Single blinded

Blinding description
The nurse will use chlorhexidine 2% solution for disinfection of the catheterization site in the intervention group 1 and will use the usual method named Betadine-Alcohol in the Intervention group 2. Parents of Neonate with informed consent and awareness of intervention will be kept unaware of being neonates in either intervention groups 1 or 2.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Alborz University of Medical Sciences

Street address
Deputy of research and technology; Safarian alley; Golshahr street; Shahid Beheshti boulevard

City
Karaj

Province
Alborz

Postal code
3198764653

Approval date
2019-09-14, 1398/06/23

Ethics committee reference number
IR.ABZUMS.REC.1398.105

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
The Nurse will check the Catheter site before each injection of the Drug and every 8 hours (According to the Hospital Policy, the maximum life expectancy of peripheral vascular catheter in Neonates is 72 hours)

Method of measurement
Standard Phlebitis Tool

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:The Skin of the Catheterization area is disinfected with Chlorhexidine Gluconate 2% solution

Category
Prevention

2

Description
Intervention group:The Skin of the Catheterization area is first disinfected with Iodine 10%, then allowed to dry and after that Iodine will be removed by Alcohol 70% and

when it dry , the Catheterization will be done

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali Hospital

Full name of responsible person

Zahra Tayebi Myaneh

Street address

Alborz School of Nursing; Golestan 1 avenue; Baghestan boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Alborz University of Medical Sciences

Full name of responsible person

Mohamad Norysepehr

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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

Alborz University of Medical Sciences

Proportion provided by this source

80

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

Alborz University of Medical Sciences

Full name of responsible person

Zahra Tayebi Myaneh

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

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Latest degree

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Other areas of specialty/work
Nursery

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Email

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