

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The comparison of chlorhexidine with povidone-iodine alcohol on bacterial colonization after peripheral vascular catheter insertion

Protocol summary

Summary

these study has been planned for comparing the effect of chlorhexidine and Povidone-iodine alcohol on bacterial colonization due to peripheral vascular catheter insertion in premature infants. All premature infants admitted with gestational age < 37 weeks, before catheter insertion will be randomly assigned to 2 groups. For half of infants (group 1) chlorhexidine gluconate and for another half (group 2) Povidone-iodine alcohol will be used for skin disinfection at peripheral catheter insertion site. After 48 hours of catheterization, catheter will be removed and culture will be done from the catheter tip.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2017062034653N1**

Registration date: **2017-08-09, 1396/05/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-09, 1396/05/18

Registrant information

Name

Zahra Tayebi Myaneh

Name of organization / entity

Qazvin University of medical science

Country

Iran (Islamic Republic of)

Phone

+98 28 3224 8614

Email address

z.tayebi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

investigator

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of chlorhexidine with povidone-iodine alcohol on bacterial colonization after peripheral vascular catheter insertion

Public title

The comparison of chlorhexidine and povidone-iodine alcohol on bacterial colonization after peripheral vascular catheter insertion .

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Premature infants in intensive care units; Infants who need vascular catheter insertion for the first time; Absence of inflammation in the vein site; No symptoms of septicemia; No bacteremia. Exclusion criteria: Failure to catheterization after first try; Use an antiseptic solution at the place of catheterization twice or more.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

The quadruple blocking method was used.

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Etics committee of Qazvin University of medical science

Street address

University of medical science, Shahid bahonar bolvar, Qazvin.s.

City

Qazvin

Postal code

Approval date

2016-11-01, 1395/08/11

Ethics committee reference number

IR.QUMS.REC.1395.178

Health conditions studied

1

Description of health condition studied

skin disinfection

ICD-10 code

B95-B98

ICD-10 code description

These categories should never be used in primary coding. They are provided for use as supplementary or additional codes when it is desired to identify the infectious agent(s) in diseases classified elsewhere.

Primary outcomes

1

Description

number of colonization

Timepoint

72 hours after culturing from catheter tip

Method of measurement

Control the number of colonies grown in culture environment

Secondary outcomes

1

Description

Type of colonies grown

Timepoint

72 hours after catheter tip sampling

Method of measurement

Control the number of colonies grown in culture environment

Intervention groups

1

Description

control group: used Povidone10% -iodine alcohol 70% for skin disinfection for peripheral catheter placement.

Category

Prevention

2

Description

intervention group: In the intervention group, the infants entering the study were treated with 2% chlorhexidine, antiseptic venulation, and then catheterization.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Educational and treatment center (NICU)

Full name of responsible person

Zahra Tayebi

Street address

Kosar Hospital, Valiasr Street, Qazvin

City

qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Researcher is sponser-

Full name of responsible person

Amir pymani

Street address

Qazvin university of medical science, Shahid bahonar bolvar.

City

Qazvin

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Researcher is sponser-

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**

Qazvin University of medical science

Full name of responsible person

Zahra Tyebi Myaneh

Position

Masters student

Other areas of specialty/work**Street address**

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Person responsible for updating data

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Position

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Fax**Email****Web page address**

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