Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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Iran (Islamic Republic of)
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+98 28 3224 8614
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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

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Person responsible for updating data

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Full name of responsible person
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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