Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of using antiseptic solutions containing chlorhexidine 2% compared to povidone-Iodine solution in disinfecting the venous catheter placement site in the incidence of catheter associated infections in admitted infantsin the neonatal intensive care unit (NICU)

Protocol summary

Study aim

Comparing the effectiveness of using disinfectant solutions containing 2% chlorhexidine versus povidone-iodine solution to prepare the skin of infants before inserting an intravenous catheter in reducing the risk of catheter-related infections by determining the effect of variables.

Design

This study is designed as a preliminary clinical trial. The total sample size for this study is calculated as 100 infants. A controlled, parallel-group, double-blind, randomized, phase 2 clinical trial on 110 patients. The rand function of Excel software was used for randomization.

Settings and conduct

The study was conducted as a pilot, randomized clinical trial on infants hospitalized in the Mahdieh Hospital NICU. Informed consent was obtained from the parents.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Neonates with a gestational age of less than 34 weeks, negative peripheral blood culture and initial CRP, hospitalization for at least 6 days in the NICU, and need for an indwelling intravenous catheter to receive fluids and medication. Exclusion criteria: Lack of consent of the infant's parents to participate in the study, death of the infant before 6 days of hospitalization, positive peripheral blood culture and CRP before catheter insertion, catheter removal before 6 days from the body.

Intervention groups

Intervention group, using 2% chlorhexidine solution and control group, using Betadine

Main outcome variables

Diagnosis at admission, type of delivery, gestational age, birth weight, birth height, birth Apgar, maternal diseases, infant age at catheter insertion, duration of catheter instillation in the infant, type of disinfectant solution, peripheral blood culture and CRP before catheter insertion, catheter culture after removal, peripheral blood culture 6 days after catheter insertion, skin culture immediately after disinfection, occurrence of contact dermatitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260108068588N1**
Registration date: **2026-02-10, 1404/11/21**
Registration timing: **prospective**

Last update: **2026-02-10, 1404/11/21**
Update count: **0**

Registration date

2026-02-10, 1404/11/21

Registrant information

Name

Golab Bostanchi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5506 2628

Email address

gbos8805@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2026-02-11, 1404/11/22
Expected recruitment end date
2026-02-14, 1404/11/25
Actual recruitment start date
2026-02-11, 1404/11/22
Actual recruitment end date
2026-02-14, 1404/11/25
Trial completion date
2026-02-16, 1404/11/27

Scientific title
Investigating the effect of using antiseptic solutions containing chlorhexidine 2% compared to povidone-Iodine solution in disinfecting the venous catheter placement site in the incidence of catheter associated infections in admitted infantsin the neonatal intensive care unit (NICU)

Public title
Comparison of the effects of chlorhexidine 2% and betadine in disinfecting the insertion site of indwelling venous catheters in neonates admitted to the neonatal intensive care unit during the hospitalization period.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Newborns admitted to the neonatal intensive care unit Newborns requiring indwelling intravenous catheters during their stay in the neonatal intensive care unit Preterm newborns
Exclusion criteria:
Parents' lack of consent to the infant's inclusion in the study No need for hospitalization for more than 3 days in the neonatal intensive care unit Evidence of sepsis before intravenous catheter placement in the neonate
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **100**
Actual sample size reached: **110**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization and assignment of infants to the intervention and control groups is determined using computer-generated random numbers. Even numbers are placed in the intervention group and odd numbers are placed in the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
None of the patients, sampling people and interpreters of the tests will be informed about the placement of the patients in the control or intervention group until the publication of the results of the study. The person taking the sample, without knowing the group of the newborns, only prepares the skin culture, peripheral blood and catheter samples and sends them to the laboratory, and the person reviewing the tests, without knowing the placement of the baby in each group, only interprets and reports the results of the tests.
Placebo
Not used
Assignment
Parallel
Other design features
-

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
6th floor, Shahid Beheshti University of Medical Sciences and Health Services, Shahid Beheshti University of Medical Sciences and Health Care Services, Shahid Chamran Highway, Yemen St., 6th Floor
City
Tehran
Province
Tehran
Postal code
1985717434
Approval date
2026-01-27, 1404/11/07
Ethics committee reference number
IR.SBMU.MSP.REC.1404.718

Health conditions studied

1

Description of health condition studied
Catheter-related bloodstream infections
ICD-10 code
B99
ICD-10 code description
Other and unspecified infectious diseases

Primary outcomes

1

Description
Gestational age
Timepoint
Weeks from fertilization
Method of measurement
Pregnancy Calendar

2

Description
Durability of the catheter in the infant's body
Timepoint
Days with a catheter in the body
Method of measurement
Difference between catheter insertion and removal dates

3

Description
Peripheral blood culture
Timepoint
6 days after catheter insertion
Method of measurement
Blood sample

4

Description
Catheter culture after removal
Timepoint
After catheter removal
Method of measurement
Peripheral blood culture tests, catheter culture, skin culture

5

Description
Skin culture immediately after disinfection
Timepoint
Immediately after disinfection
Method of measurement
A sterile cotton swab is applied to the disinfected skin and sent for culture.

Secondary outcomes

1

Description
Contact dermatitis
Timepoint
Within 1 to 5 days after disinfection
Method of measurement
Observation

Intervention groups

1

Description
Intervention group: Infants who received 2% chlorhexidine solution to disinfect the intravenous catheter insertion site.
Category
N/A

2

Description
Control group: Use of povidone iodine solution to disinfect the catheter insertion site.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdieh Hospital
Full name of responsible person
Dr Naeemeh Taslimi Taleghani
Street address
Mahdieh Hospital, Rajab-nia St., Fadaeeian-e-islam ave., Shush Square, Tehran.
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mahdiyeh_hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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7th floor, Bldg No.2 Shahid Beheshti University of Medical Sciences, Arabi ave, Velenjak, Tehran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
No
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Golab Bostanchi
Position
Resident (Specialist medical assistant)
Latest degree
Medical doctor
Other areas of specialty/work
Pediatrics
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Mahdieh Hospital, Rajab-nia St., Fadaeeian-e-islam ave,. Shush Square., Tehran
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The results will be published in the form of statistical data analyzed by computer software along with explanations. Confidential principles are included in all information.
When the data will become available and for how long
Access starts 1 month after results are published.
To whom data/document is available
The data will be available only to researchers working in

academic and scientific institutions.

Under which criteria data/document could be used

The data can be used for reference in future studies.

From where data/document is obtainable

Please refer to the e-mail of Dr. Golab Bostanchi, responsible for the public response of the study, with the following address. gbos8805@gmail.com

What processes are involved for a request to access data/document

The applicant is required to provide me with a summary of the upcoming research project and to send full academic specifications and academic degree.

Comments