

# 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 scientific inquiries

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### Person responsible for updating data

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**Full name of responsible person**

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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*