# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

26 May 2026

## A clinical trial comparing the local effects of breast milk, chlorhexidine, and drying on bacterial colonization in umbilical cord of preterm neonates hospitalized in the neonatal intensive care unit

## Protocol summary


**Summary**

This clinical trial compares the effects of breast milk, chlorhexidine, and drying on the bacterial colonization of the umbilical cord in premature infants. The trial is one-centered, single-blind, and in phase 2 of clinical trials. The major inclusion criteria are gestational age less than 37 weeks and admission in the neonatal intensive care unit. Major exclusion criteria include the lack of consent of the legal guardian, approved sepsis, and the history of non-sterile childbirth in the mother. A sample of 75 preterm infants will be recruited by convenience sampling method and assigned into one of the three groups of drying, chlorhexidine, and milk by using table of random numbers (n=25 per group). During the first 12 to 24 hours of admission, umbilical cord samples will be collected from the neonates as follows. Using sterile swabs, umbilical cord samples of the infants (1 centimeter from the skin surrounding the umbilical cord) will be taken and transferred to the laboratory in phosphate buffer solution (tube containing 5 cc phosphate saline buffer with pH of 7). Then, serial dilutions will be prepared in one to ten ratio from the samples. Afterwards, 0.01 cc comprising of non-diluted specimen, one-tenth diluted specimen, and one-hundredth diluted specimen will be cultured on the agar culture medium and Eosin methylene blue agar. The plates will be kept at 37 ° Celsius for 48 hours. In terms of study interventions, in the drying group, the umbilical cord will be kept dry using sterile gauze. In the chlorhexidine group, every six hours, 2 to 3 cc of 0.2 percent chlorhexidine mouthwash will be applied onto the umbilical cord and 1 centimeter of its surrounding area proportionate to the umbilical cord size. In the breast milk group, every six hours, between 1 and 2 cc of the milk will be applied onto the umbilical cord and 1 centimeter of its surrounding area proportionate to the umbilical cord size. After 72 hours, again using a sterile swab, the umbilical cord will be sampled and cultured. The effects of the three interventions on the number of viable bacteria and type of bacteria will be investigated.


## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017090517756N27**
Registration date: **2017-10-16, 1396/07/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2017-10-16, 1396/07/24

**Registrant information**


**Name**

Mohammad Bagher Roozgar

**Name of organization / entity**

Birjand University of Medical Sciences

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**


**Funding source**

Vice-chanceller for Research, Birjand University of Medical Sciences


**Expected recruitment start date**

2017-06-22, 1396/04/01

**Expected recruitment end date**

2017-12-22, 1396/10/01

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
A clinical trial comparing the local effects of breast milk, chlorhexidine, and drying on bacterial colonization in umbilical cord of preterm neonates hospitalized in the neonatal intensive care unit

**Public title**
Effects of breast milk, chlorhexidine, and drying on bacterial infection in umbilical cord
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
Inclusion criteria: Gestational age less than 37 weeks ; need for admission in the neonatal intensive care unit; treatment with ampicillin and gentamicin antibiotics.
Exclusion criteria: Dissatisfaction of the legal guardian(s) for participation; confirmed sepsis before bacterial culture; history of non-sterile childbirth; presence of anatomical malformation;history of perinatal asphyxia; presence of symptoms of omphalitis before the test; history of infections in the mother during pregnancy; prescribed antibiotics in the mother before delivery; prolonged rupture of fetal membranes; umbilical catheterization; any umbilical intervention during hospitalization; chorioamononitis
**Age**
From **1 day** old to **1 day** old
**Gender**
Both

**Phase**
2
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **75**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**
Allocation of the subjects into study groups is via table of random numbers.

## Secondary Ids

empty

## Ethics committees

**1**

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Birjand University of Medical Sciences
**Street address**
Vice-chancellery for Research, Birjand University of Medical Sciences, Ghaffari St.,
**City**
Birjand,
**Postal code**
**Approval date**
2017-06-07, 1396/03/17
**Ethics committee reference number**
Ir.bums.REC.1396.63

## Health conditions studied

**1**

**Description of health condition studied**
Bacterial colonization
**ICD-10 code**
A49.9
**ICD-10 code description**
Bacterial infection, unspecified

## Primary outcomes

**1**

**Description**
Density of bacteria
**Timepoint**
Before and 72 hours after the intervention initiates
**Method of measurement**
Laboratory tests in terms of colony-forming unit per square centimeter

**2**

**Description**
Species of bacteria
**Timepoint**
Before and 72 hours after the intervention initiates
**Method of measurement**
Laboratory tests

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention Group 1 (Drying): During the first 12 to 24 hours of admission, umbilical cord samples will be

collected from the neonates using a sterile swab. In this group, the umbilical cord will be kept dry using sterile gauze. After 72 hours, again using a sterile swab, the umbilical cord will be sampled and cultured.

**Category**

Prevention

**2**

**Description**

Intervention Group 2 (Chlorhexidine): During the first 12 to 24 hours of admission, umbilical cord samples will be collected from the neonates using a sterile swab. In this group, every six hours, 2 to 3 cc of 0.2 percent chlorhexidine mouthwash will be applied onto the umbilical cord and 1 centimeter of its surrounding area proportionate to the umbilical cord size. After 72 hours, again using a sterile swab, the umbilical cord will be sampled and cultured.

**Category**

Prevention

**3**

**Description**

Intervention Group 3 (Mother's breast milk): During the first 12 to 24 hours of admission, umbilical cord samples will be collected from the neonates using a sterile swab. In this group, every six hours, between 1 and 2 cc of the mother’s breast milk will be applied onto the umbilical cord and 1 centimeter of its surrounding area proportionate to the umbilical cord size. After 72 hours, again using a sterile swab, the umbilical cord will be sampled and cultured.

**Category**

Prevention

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Valiasr Hospital

**Full name of responsible person**

Dr. Mozhgan Yaghoobi

**Street address**

Ghafari Street,

**City**

Birjand,

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Vice-Chancellery for Research and Technology, Birjand University of Medical Sciences

**Full name of responsible person**

Dr Tooba Kazemi

**Street address**

Vice-chancellery for Research, Birjand University of Medical Sciences, Ayatollah Ghafari Street,

**City**

Birjand,

**Grant name**

**Grant code / Reference number**

-

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

Yes

**Title of funding source**

Vice-Chancellery for Research and Technology, Birjand University of Medical Sciences

**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**

Birjand University of Medical Sciences

**Full name of responsible person**

Dr Mozhgan Yaghoobi

**Position**

Resident of Pediatrics

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## 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*