Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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

Other areas of specialty/work

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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