Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of topical application of breast milk on bacterial colonization and umbilical cord separation time in neonates in comparison to dry cord care

Protocol summary

Summary

The purpose of this study was comparing the effect of topical application of breast milk and dry cord care on bacterial colonization and cord separation time in neonates. In a longitudinal study, 118 newborn neonates were investigated at Omolbanin Hospital in Mashhad, Iran. We assigned them into two groups (case and control) randomly. In case group, breast milk was used on cord 3 hours after birth and then every 12 hours until 2 days after cord separation. In control group, no substance was used and cord was sustained dry. Researcher obtained an umbilical swab from base of the cord three hours after birth and in the third day of life and called mother to record cord separation time. Rate of bacterial colonization and cord separation time were measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138708071162N7**
Registration date: **2009-01-15, 1387/10/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2009-01-15, 1387/10/26

Registrant information

Name
Ashraf Mohammadzadeh
Name of organization / entity
Neonatal Research Center of Mashhad University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

mashhad university of medical science

Expected recruitment start date

2007-02-08, 1385/11/19

Expected recruitment end date

2007-08-10, 1386/05/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of topical application of breast milk on bacterial colonization and umbilical cord separation time in neonates in comparison to dry cord care

Public title

The effect of topical application of breast milk on bacterial colonization and umbilical cord separation time in neonates in comparison to dry cord care

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: gestational age of 38-42 weeks, freedom from any disease or congenital anomalies. Exclusion criteria: infants with respiratory distress, perinatal asphyxia, metabolic derangement and any other problems requiring immediate evaluation and treatment, duration rupture of membrane more than 12

h, 1 and 5-min Apgar score <7, genitourinary system infection.

Age
From **1 year** old to **21 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **118**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice chancellor for research of Mashhad University of medical sciences

Street address
Ghoreshi building, Daneshgah street, mashhad, Iran

City
Mashhad

Postal code
13131-91379

Approval date
2007-02-03, 1385/11/14

Ethics committee reference number
10328/51

Health conditions studied

1

Description of health condition studied
bacterial colonization

ICD-10 code
B99

ICD-10 code description
Other infectious diseases

2

Description of health condition studied
umbilical cord separation time

ICD-10 code
L80-L99

ICD-10 code description
Other disorders of the skin and subcutaneous tissue

Primary outcomes

1

Description
Decreasing infection

Timepoint
3 hour after birth and 3 day after birth

Method of measurement
Umbilical swab from the base of cord

Secondary outcomes

1

Description
Decreasing umbilical cord separation time

Timepoint
Daily

Method of measurement
Report of mother for umblical cord separation

Intervention groups

1

Description
In control group, no substance was used and cord was sustained dry

Category
N/A

2

Description
In case group, breast milk was used on cord 3 hours after life and then every 12 hours until 2 days after cord separation

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Omolbanin Hospital

Full name of responsible person
Dr.Ashraf mohammadzadeh

Street address
Neonatal research center- NICU- Emamreza hospital-mashhad-Iran

City
mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
mashhad university of medical science
Full name of responsible person
Dr jalil tavakol afshari
Street address
ghoreshi bulding-daneshgah street-mashhad-Iran
City
mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
mashhad university of medical science
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
Neonatal Research Center
Full name of responsible person
Dr. Ashraf mohammadzadeh
Position
Neonatologist, professor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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