

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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)

Phone

+98 51 1852 1121

Email address

mohamadzadeha@mums.ac.ir

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 umbilical 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 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