

# 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****Street address**

NRC-NICU-Emamreza hospital-mashhad-Iran

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

Dr.Ashraf mohammadzadeh

**Position**

Neonatologist, professor

**Other areas of specialty/work****Street address**

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mohammadzadeh\_ashraf@yahoo.com

**Web page address**

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## Person responsible for updating data

#### Contact

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Neonatal Research Center

**Full name of responsible person**

Dr.Ashraf mohammadzadeh

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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*