

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of topical application of breast milk and routine procedure on umbilical cord separation time and the bacterial colonization in very Low Birth Weight (VLBW) Infants

Protocol summary

Summary

In a randomized clinical trial on preterm infants (weighing less than 1500 grams) admitted to NICU and internal NICUs of Alzahra and Shahid Beheshti hospitals in Isfahan, the effect of topical use of breast milk on separation time of umbilical cord and bacterial colonization is investigated. The criteria for entering this study are premature neonates, weighing less than 1500 grams and criteria for exclusion from the study are congenital major anomalies, Asphyxia, hypoxia, and umbilical catheter insertion. A sample of 32 patients in each group was calculated according to the related equation. these infants are divided into 2 groups of topical use of breast milk on umbilical cord (M) and dry care group (D). In group (M) 3-4 drops of breast milk are applied to the umbilical cord within 8 hours of birth, and this is continued every 8 hours to two days after separation of the umbilical cord. in group (D) umbilical cord is exposed to the open air to dry gradually and does not use any substance. (Conventional routine). 3 samples of cultivated swab were taken from the umbilical cord of each infant (2-4 hours after birth, after 3 days, day of umbilical cord separation) to check for bacterial colonization. Neonates in both groups will be monitored for symptoms of omphalitis, bad smell, exudates, granulation tissue and sepsis. Then the information of each infant is recorded in the questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052110026N8**
Registration date: **2017-09-19, 1396/06/28**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-09-19, 1396/06/28

Registrant information

Name

Amir mohammad Armanian

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1235 5059

Email address

armanian@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences, Isfahan, Iran

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of topical application of breast milk and routine procedure on umbilical cord separation time and the bacterial colonization in very Low Birth Weight (VLBW) Infants

Public title

Effect of topical application of breast milk on umbilical

cord separation time in very Low Birth Weight (VLBW) Infants

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria for this study: preterm birth (prematurity), weighing less than 1500 grams Exclusion criteria for this study: major congenital anomalies, presence of asphyxia and hypoxia, umbilical catheter

Age

To **1 month** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

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

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezarjerib st.

City

Isfahan

Postal code

Approval date

2013-11-02, 1392/08/11

Ethics committee reference number

292143

Health conditions studied

1

Description of health condition studied

Neonatal skin infection

ICD-10 code

p39.4

ICD-10 code description

Neonatal skin infection

Primary outcomes

1

Description

day of umbilical cord separation

Timepoint

at the 3th and 7th days of life

Method of measurement

daily recorded sheets

Secondary outcomes

1

Description

bacterial colonization

Timepoint

at the 3th, 7th days of life

Method of measurement

swap- culture

2

Description

omphalitis

Timepoint

at the 3th, 7th days of life

Method of measurement

daily recorded sheets

3

Description

exudate

Timepoint

at the 3th, 7th days of life

Method of measurement

daily recorded sheets

4

Description

granulation tissue

Timepoint

at the 3th, 7th days of life

Method of measurement

daily recorded sheets

5

Description

sepsis

Timepoint

at the 3th, 7th and 15th days of life

Method of measurement

daily recorded sheets

Intervention groups

1

Description

In the control group (dry care), the umbilical cord is allowed to dry in open air gradually. Then, within 2-4 hours after birth, a culture swab from the umbilical stump is sent to laboratory as baseline. Then, two other culture swabs from the umbilical stump, one at 3 days after birth and the other on the day that the umbilical cord was removed is sent to check bacterial colonization.

Category

Prevention

2

Description

In the intervention group (breast milk use on the umbilical cord) 3-4 drops of breast milk for a maximum of 8 hours after birth is rubbed on umbilical stump. This will continue every 8 hours to two days after cord separation. Then, within 2-4 hours after birth, a culture swab from the umbilical stump is sent to laboratory as baseline. Then, two other culture swabs from the umbilical stump, one at 3 days after birth and the other on the day that the umbilical cord was removed is sent to check bacterial colonization.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

NICU of Shahid Beheshti Hospital

Full name of responsible person

Dr. Amir Mohammad Armanian

Street address

Number 133, Shahid Ansari Alley, Saeb street,
Isfahan, Iran

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Ebrahim Esfandiari

Street address

Isfahan University of Medical Sciences, Hezar Jirib,
Isfahan

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Isfahan 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

Department of pediatrics , Isfahan University of
Medical Sciences, Isfahan, Iran

Full name of responsible person

Dr. Amir Mohammad Armanian

Position

Associate professor of neonatology

Other areas of specialty/work

Street address

Number 133, Shahid Ansari Alley, Saeb street

City

Isfahan

Postal code

Phone

+98 131294044

Fax

Email

armanian@med.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Child Growth and DeveLopment Research Center
, Isfahan University of Medical Science

Full name of responsible person

Dr. Amir Mohammad Armanian

Position

Associate professor of neonatology

Other areas of specialty/work

Street address

Number 133, Shahid Ansari Alley, Saeb street

City

Isfahan

Postal code

Phone

+98 31 3235 5059

Fax

Email

armanian@med.mui.ac.ir

Web page address

Email

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr. Amir Mohammad Armanian

Position

Associate professor of neonatology

Other areas of specialty/work

Street address

Number133, Shahid Ansari Alley, Saeb street

City

Isfahan

Postal code

Phone

Fax

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