Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 (pre-maturity), 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

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

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Phone

Fax

Email

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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