Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of topical application of human milk ,chlorhexidin and dry cord care on the cord-separation time and bacterial colonization of cord of newborn

Protocol summary

Summary

The aim of this study is to compare the impact of three regimens of cord care, topical use of human milk, chlorhexidin solution and dried cord care on the cord-separation time and occurrence of bacterial colonization among neonates. A total of 261 neonates (87 neonates in each group) will be enrolled in this randomized clinical trial. Neonates with gestational age of 42-37 weeks, which no immediate need of evaluation and treatment of the newborn, will be examined. The infants will be randomly assigned into three groups of cord care regimens: topical application of human milk (case group), topical chlorhexidine solution (case group) and dried cord care (control group). In group topical application of human milk, all mothers will be rubbed its own milk, and In group chlorhexidine, chlorhexidine solution 4% with a cotton swab on the abdominal skin around the base and cord stump thoroughly from three hours after birth every 12 hours to 2 days after the umbilical cord separation .In group dried cord, mother are recommended that don't used any material on cord. In order to make sure of the presence of the microorganisms, samples of the cord stump will be collected using sterile swabs within the first three hours after birth and other visits (days 3, 7 and 2 days after umbilical cord separation).. Researchers asked the exact date and time of the cord separation via telephone and in cases of delay in cord separation or any cord related adverse events, the newborn will be immediately visited by neonatologist.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010285038N1**
Registration date: **2012-10-25, 1391/08/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-10-25, 1391/08/04

Registrant information

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Recruitment status

Recruitment complete

Funding source

the Research Deputy of Kashan University of Medical Sciences

Expected recruitment start date

2010-12-14, 1389/09/23

Expected recruitment end date

2011-12-29, 1390/10/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of topical application of human milk ,chlorhexidin and dry cord care on the cord-

separation time and bacterial colonization of cord of newborn

Public title
The effect of topical application of human milk ,chlorhexidinon on umbilical cord of newborn
Purpose
Prevention
Inclusion/Exclusion criteria
Criteria for Inclusion: Newborns with gestational age 42-37 weeks; Apgar score higher than 7 at minute 1; rupture of membranes for no longer than 12 hours; The cord cut in sterile condition in the delivery room and don't use antiseptic agent on the stump. criteria for excluded: Infants with perinatal asphyxia, respiratory distress, metabolic disease, and any other problems that requiring immediate refer to neonatal Intensive Care Unit ; Infants with immediate need of evaluation and treatment; Newborns with any congenital disorder or disease; Infants of mothers with postpartum fever, mastitis, Urogenital infection; If the mother does not live in the city of Kashan(live in Rural); If the mother is the Afghani.
Age
To **1 year** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **261**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Deputy of kashan University of Medical Sciences
Street address
5th of Qotb –e Ravandi Blvd. P.O.Box: 87155.154, Kashan, IRAN
City
kashan
Postal code
88141/87159
Approval date
2010-09-14, 1389/06/23
Ethics committee reference number
1781/1/5/29/پ

Health conditions studied

1

Description of health condition studied
Certain conditions originating in the perinatal period
ICD-10 code
P38
ICD-10 code description
Omphalitis of newborn with or without mild haemorrhage

Primary outcomes

1

Description
umbilical cord separation time
Timepoint
from birth to Cord separation time
Method of measurement
Researcher observed

2

Description
infection Umbilical cord
Timepoint
the first three hours after birth , days 3 and 7 after intervention ,2 days after umbilical cord separation
Method of measurement
Culture of samples

Secondary outcomes

1

Description
Complications and problems such as leakage of blood, discharge and granuloma tissue
Timepoint
the first three hours after birth , days 3 and 7 after intervention ,2 days after umbilical cord separation
Method of measurement
Observed by the researcher and visited by neonatologist if there is any cord related adverse events

Intervention groups

1

Description
Intervention GROUP:In group topical application of human milk of all mothers will be advised after washing hands with soap and water, she will rub its own milk to

cord stump from three hours after birth every 12 hours (2 times a day) to 2 days after the umbilical cord separation and allow the milk of the cord is completely dry

Category
Other

2

Description
Intervention GROUP:In group chlorhexidine mother will wet a cotton swab by placing it on the mouth of the chlorhexidine bottle 4% (30 ml bottle) and inverting the bottle. Then gently will rub the abdominal skin around the base and cord stump thoroughly, ensuring that the entire area was covered with solution. A second cotton swab will similarly moistened and used to cleanse the tip of the cord (if not yet separated) or the middle of the cord stump (if separation had occurred). she will rub its from three hours after birth every 12 hours (2 times a day) to 2 days after the umbilical cord separation

Category
Other

3

Description
In group dry cord(control group), mother will recommend that is not used any material on cord

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Shabikhani Hospital of Kashan-Behesht Hospitals of Kashan

Full name of responsible person
Abbaszadeh Fatemeh

Street address

City
kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
Gholam Ali Hamidi

Street address
Department of Physiology & Pharmacology, Kashan University of Medical Sciences, Kashan, Iran

City
Kashan

Grant name

Grant code / Reference number

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

Title of funding source
Kashan 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
kashan University of Medical Sciences

Full name of responsible person
Fatemeh Abbaszadeh

Position
msc-Faculty member

Other areas of specialty/work

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Person responsible for scientific inquiries

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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