Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of breast milk topical application, 96% ethyl alcohol and natural dry care on the timing of umbilical cord separation in healthy and term newborns.

Protocol summary

Summary

Comparing the effect of breast milk topical application, 96% ethyl alcohol and natural dry care on the timing of umbilical cord separation in healthy and term newborns. The aim of this study is to compare the effect of breast milk topical application, 96% ethyl alcohol, and natural dry care on the timing of umbilical cord separation in healthy and term newborns. In this randomized study 207 neonates (69 neonates in each group) will be studied. Right after birth newborns will be allocated randomly to one of the three groups: breast milk topical application (case group) , 96% ethyl alcohol topical application (case group) and natural drying keep the umbilical cord (control group). In brest milk topical application group, mother's own milk, and in ethyl alcohol group, 96% ethyl alcohol from three hours after birth every 12 hours to 2 days after the umbilical cord separation will be rubbed to umbilical cord remaining part and it's cutted edge. In the group of natural dry care of the umbilical cord, we will recommend to mother not to use anything on the umbilical cord. The researcher will ask exact date and time of umbilical cord separation from mother through telephone .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013042813157N1**
Registration date: **2013-11-11, 1392/08/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-11-11, 1392/08/20

Registrant information

Name
Khadijeh Ghoreishi
Name of organization / entity
Hamedan University of Medical Science
Country
Iran (Islamic Republic of)
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00988118380436, 00988118380573
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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2013-02-14, 1391/11/26

Expected recruitment end date

2013-06-16, 1392/03/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of breast milk topical application, 96% ethyl alcohol and natural dry care on the timing of umbilical cord separation in healthy and term newborns.

Public title

The effect of breast milk, alcohol and natural dry care on the timing of umbilical cord separation.

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria: healthy and term newborns with

gestational age with 37-42 weeks. Exclusion criteria: newborns with any congenital disorder or disease, newborns with respiratory distress, perinatal asphyxia, newborns with urgent need to evaluation and treatment, metabolic disease, and any other problem which has immediate need to transfer to neonatal intensive care unit.

Age
To **1 year** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **207**

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 Hamedan University of Medical Science

Street address
Shahid Fahmideh Blvd, Front Mardom Park, Hamedan University of Medical Science, Hamedan

City
Hamedan

Postal code
65178

Approval date
2013-02-14, 1391/11/26

Ethics committee reference number
4023/9/35/16/پ

Health conditions studied

1

Description of health condition studied
Umbilical cord care

ICD-10 code
P96.9

ICD-10 code description
Condition originating in the perinatal period, unspecified

Primary outcomes

1

Description
Umbilical cord separation time

Timepoint
From birth to umbilical cord separation time

Method of measurement
Observation in hours

Secondary outcomes

1

Description
Bleeding continuation after umbilical cord separation.

Timepoint
After umbilical cord separation

Method of measurement
Observation

Intervention groups

1

Description
Intervention group1: In breast milk topical application group we will ask all mothers to rub their milk to umbilical cord stump every 12 hours (2 times a day) from three hours after birth until 2 days after the umbilical cord separation after washing their hands with water and soap.

Category
Other

2

Description
Intervention group2: In 96% ethyl alcohol topical application group we will ask all mothers to moisten a cotton swab by placing it on the mouth of the ethyl alcohol bottle, then gently rub it completely on the skin of abdomen around and stump of umbilical cord every 12 hours (2 times a day) from three hours after birth until 2 days after the umbilical cord separation .

Category
Other

3

Description
Control group: In natural dry care group we will ask mothers not to use anything on umbilical cord stump

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemieh Hospital of Hamedan
Full name of responsible person
Ghoreishi Khadijeh
Street address
Pasdaran street, Shariati Square, Hamedan
City
Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research of Hamedan University of Medical Science
Full name of responsible person
Godarzi Mohammad Taghi
Street address
Shahid Fahmideh Blvd, Front Mardom Park, Hamedan University of Medical Science, Hamedan
City
Hamedan

Grant name
ندارد
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Hamedan 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
Besat Hospital of Hamedan
Full name of responsible person
Ghoreishi Khadijeh
Position
General Physician
Other areas of specialty/work
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Person responsible for scientific inquiries

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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