

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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 breast 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)

Phone

00988118380436, 00988118380573

Email address

besat@umsha.ac.ir

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**Street address**

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Postal code

6514845471

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+98 811264002051

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+98 81 1265 1515

Email

Qoreishi372@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Besat Hospital of Hamedan

Full name of responsible person

Eghbalian Fatemeh

Position

Faculty Member

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

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Besat@umsha.ac.ir

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Person responsible for updating data

Contact

Name of organization / entity

Besat Hospital of Hamedan

Full name of responsible person

Ghoreishi Khadijeh

Position

General physician

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

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Web page address

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