

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jul 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

###### Name

Fatemeh Abbaszadeh

###### Name of organization / entity

kashan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 36 1534 3630

###### Email address

abbaszadeh\_f@kaums.ac.ir

##### 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**

**Street address**

5th of Qotb -e Ravandi Blvd. P.O.Box: 87155.154, Kashan, IRAN

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**Person responsible for scientific inquiries**

**Contact**

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## **Person responsible for updating data**

### **Contact**

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kashan University of Medical Sciences

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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*