Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of topical use of breast milk on episiotomy healing in Primiparous women at high risk for wound infection

Protocol summary

Study aim

Determining the effect of topical use of breast milk on episiotomy healing in Primiparous women at high risk for wound infection

Design

Clinical trial, superiority, with intervention and control groups, without blinding, simple random assignment, on 72 patients, www.randomization.com was used for randomization.

Settings and conduct

The present study will be performed in the maternity ward of Umm Al-Banin Hospital in Mashhad. In the intervention group, in addition to routine rinsing of the perineal episiotomy with 9% non-injectable normal saline, 2 ml is infused on the perineal wound site and 0.25 ml in the first three days. Gently squeeze with gas for 3 minutes and the control group will perform routine care. The episiotomy site will be examined in the first 24 hours, on the fifth and tenth days, and its improvement will be scored according to the REEDA scale. research units complete the follow-up checklist during the study period and deliver it to the researcher on days five and ten

Participants/Inclusion and exclusion criteria

The gestational age is between 38 to 42 weeks ؛Vaginal delivery؛ Be primiparous؛ Episiotomy incision should be of the mediultral type؛ Have at least two conditions predisposing to infection at the same time؛ The episiotomy is first and second degree

Intervention groups

In the intervention group, topical application of episiotomy with breast milk, in addition to routine rinsing of the perineum with normal saline, is performed for ten days, and in the control group, only routine rinsing of the perineum with normal saline is performed during the same period

Main outcome variables

The interval between rupture of the amniotic sac and the time of delivery; BMI; Number of vaginal examinations; The distance between the two cutting edges before skin repair; Number of skin sutures; Observance of hygienic principles; Use of antibiotics; Suture opening; Wound infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210121050098N1**
Registration date: **2021-03-24, 1400/01/04**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-24, 1400/01/04**
Update count: **0**

Registration date

2021-03-24, 1400/01/04

Registrant information

Name

Kobra Sadat Hosseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3859 1511

Email address

hoseinik973@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-05-20, 1400/02/30

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of topical use of breast milk on episiotomy healing in Primiparous women at high risk for wound infection

Public title
The effect of topical use of breast milk on episiotomy healing in Primiparous women at high risk for wound infection
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Iranian nationality and resident of Mashhad Have at least literacy Have informed consent to participate in the research The gestational age is between 38 - 42 weeks The fetus is single and alive Show the fetus at the top of the head Vaginal and spontaneous delivery has been performed Be primiparous Episiotomy incision should be of the mediultral type Have at least two conditions predisposing to infection at the same time The episiotomy is first and second degree
Exclusion criteria:
Do follow a special diet . such as a diet of vegetables or just meat Do use tobacco or drugs The fetus does suffer from severe and persistent respiratory distress Do use certain medications (including anticoagulants, antidepressants, antiepileptics, alcohol and benzodiazepines) Use of assistive devices in natural childbirth The death of a baby or infant with major abnormalities Have a history of reconstructive surgery and vaginal and perineum lesions
Age
From **15 years** old to **49 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **72**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling is available by simple random assignment. After determining the sample size, through a table of random numbers using the site www.randomization.com, the numbers are divided into two groups of sequences marked with the letters A and B. The sequence stored in sealed envelopes that the researcher uses when selecting a research unit to send individuals to two groups that meet the inclusion criteria.
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 Mashhad University of Medical Sciences, School of Nursing and Midwifery
Street address
School of Nursing and Midwifery, Doktora Crossroads, Daneshgah St., Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2020-12-29, 1399/10/09
Ethics committee reference number
IR.MUMS.NURSE.REC.1399.071

Health conditions studied

1

Description of health condition studied
episiotomy wound healing
ICD-10 code
O86.0
ICD-10 code description
Infection of obstetric surgical wound

Primary outcomes

1

Description
Redness
Timepoint
The first 24 hours, the fifth and tenth days after delivery
Method of measurement
REEDA Scale

2

Description
Edema
Timepoint
The first 24 hours, the fifth and tenth days after delivery
Method of measurement
REEDA Scale

3

Description
Ecchymosis
Timepoint
The first 24 hours, the fifth and tenth days after delivery
Method of measurement
REEDA Scale

4

Description
Discharge
Timepoint
The first 24 hours, the fifth and tenth days after delivery
Method of measurement
REEDA Scale

5

Description
Approximation
Timepoint
The first 24 hours, the fifth and tenth days after delivery
Method of measurement
REEDA Scale

Secondary outcomes

1

Description
The rate of episiotomy healing in women at high risk for wound infection
Timepoint
The first 24 hours, days five and ten after delivery
Method of measurement
REEDA Scale

Intervention groups

1

Description
Intervention group: In addition to routine rinsing of the perineal episiotomy with normal saline 9% non-injectable (twice a day every 12 hours - routine washing of Mashhad training hospitals with normal saline for ten days), the perineal wound will be soaked in breast milk. This is done for ten days after delivery twice a day (every 12 hours) each time with a new 5 ml syringe at the rate of 2 ml of breast milk and with a 2 ml syringe without a needle from the first day on the perineal wound. It is instilled (in the first three days, this amount is 0.25 ml, which is instilled into the perineal wound) and then gently squeezed with gas for 3 minutes.
Category
Treatment - Other

2

Description
Control group: Recommended to wash the perineum with 9% non-injectable normal saline twice a day for ten days (according to the routine of Umm Al-Banin Hospital in Mashhad)
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ommolbanin hospital
Full name of responsible person
Faride Akhlaghi
Street address
Corner of Ayatolah Bahjat St 16, Zarrineh Crossroads, Mashhad, Khorasan Razavi, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
School of Nursing and Midwifery, Ibn Sina St., Doctora Intersection, Daneshgah St., Mashhad, Khorasan Razavi, Iran
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tafaghodim@mums.ac.ir
Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Kobra Sadat Hosseini
Position
University student
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Master
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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document

Documents are shared after being unidentified

When the data will become available and for how long

8 months

To whom data/document is available

All researchers

Under which criteria data/document could be used

All women with natural childbirth who have had an episiotomy and Midwifery service personnel

From where data/document is obtainable

To email address hoseinik973@mums.ac.ir

What processes are involved for a request to access data/document

First, send an e-mail and if you do not respond within a week, you can refer to the library of Mashhad School of Nursing and Midwifery at Ibn Sina St.

Comments