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
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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**

**Ethics committee**

**Description of health condition studied**
episiotomy wound healing

**ICD-10 code**
086.0

**ICD-10 code description**
Infection of obstetric surgical wound

**Primary outcomes**

**Description**
Redness

**Timepoint**
The first 24 hours, the fifth and tenth days after delivery

**Method of measurement**
REEDA Scale

**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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Web page address
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Sponsors / Funding sources

1
Sponsor
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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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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
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Person responsible for updating data

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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 hoseink973@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**