Clinical Trial Protocol
Iranian Registry of Clinical Trials
08 Jun 2023

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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Name of organization / entity
Iran (Islamic Republic of)
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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
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

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
086.0

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

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

### 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

### Sponsors / Funding sources

#### 1
- **Sponsor**: 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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  - **Province**: Razavi Khorasan
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  - **Email**: tafaghodim@mums.ac.ir
  - **Web page address**: https://woman.mums.ac.ir/

- **Grant name**: 
  - **Grant code / Reference number**: 
  - **Is the source of funding the same sponsor**: 

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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
Midwifery
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jahanishn@mums.ac.ir

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**