Clinical Trial Protocol  
Iranian Registry of Clinical Trials  
13 Mar 2020

Compare the effect phenytoin cream and honey cream on pain and healing of episiotomy in nulliparous women

Protocol summary

Summary
The aim of this study was to compare the effect of phenytoin cream and honey cream on pain and healing episiotomy in nulliparous women. Method: The study was a double-blind randomized clinical trial And the 120 primiparous women (40 patients in the phenytoin cream group, 40 patients in the honey cream group and 40 patients in the placebo group) Referred to a Tamin ejtemaie hospital in the city of Kashan was performed. Inclusion criteria included Term and Nulliparous Pregnancy, A literate, between 18-35 of age; race Persia; Living in Kashan; a live singleton fetus with cephalic presentation; birth weight between 2500-4000 grams; BMI In the range of 19.8 to 30 and Exclusion criteria included use of Drugs affecting the healing of wounds During the study. Not used regularly and as directed cream, sensitivity in the creams desired, lack of desire to continue participating in the study and Avoidance of referring to Hospital clinic or The nearest clinic to the home In the seventh and fourteenth days after delivery. Postpartum mothers for 10 days and once a day, a night, a finger of cream prescribed in the stitches were used. In the meantime, when discharged, for mothers routinely cephalexin capsules 500 mg every 6 hours for 8-7 days was prescribed. Evaluation of wound healing using reeda scale and pain intensity by numerical rating scale In the first 24 hours, the seventh and fourteenth days after giving birth was carried out.

General information

Acronym

IRCT registration information
IRCT registration number: IRCT201405318801N8
Registration date: 2014-09-10, 1393/06/19
Registration timing: na

Recruitment status
Not enough for processing
Funding source
Research Assistant School of Nursing and Midwifery

Expected recruitment start date
2014-02-20, 1392/12/01
Expected recruitment end date
empty
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Compare the effect phenytoin cream and honey cream on pain and healing of episiotomy in nulliparous women

Public title
Comparison of the effect of phenytoin Cream and Honey Cream on episiotomy pain and healing of episiotomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Term and Nulliparous Pregnancy; A literate; birth weight between 2500-4000 grams; BMI In the range of 19.8 to 30; The lack of effect on wound healing drugs (anticoagulants, antidepressants, anticonvulsants, alcohol, glucocorticoids, suppression of the immune system, antibiotics and chemotherapy); narcotics and psychotropic drugs; Disturbing lack of healing diseases (chronic, systemic, cardiac, renal, pulmonary, coagulation disorders, immune deficiency, connective
tissue disorders, diabetes, anemia, psychiatric disease, hemophilia, depression, malnutrition) and no history of injury, or previous surgery of lesions visible in the perineum (genital warts, hemorrhoids), persistent constipation; Lack PROM more than 18 hours; lack a history of reactions to local anesthetics or lidocaine; absence of bleeding after childbirth; lack of manual removal of the placenta; the absence of perineal hematoma; No manipulation of the perineum after delivery; failure or anomaly NICU baby; for more than 14 hours not take delivery of the first stage, second stage of labor greater than 2 hours to not take, the third stage of labor not take more than half an hour. Exclusion Criteria: Drugs affecting the healing of wounds (anticoagulants, antidepressants, anticonvulsants, alcohol,[Gkvkvrtykvyydha, suppressing the immune system, antibiotics and chemotherapy) during the study; Not used regularly and as directed cream; creams desired sensitivity; lack of desire to continue participating in the study; having sex in the first five days after birth; coming to the clinic.

Age
From 18 years old to 35 years old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: 120

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
-

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Shahid Beheshti University for Medical Sciences

Street address
tehran,shahid chamran high way, yaman street, next of taleghani hospitol, Nursing and Midwifery of Shahid Beheshti univercity

City
Tehran

Postal code

Health conditions studied

1

Description of health condition studied
Episiotomy pain and wound healing

ICD-10 code
o70.1

ICD-10 code description
Second degree perineal laceration during delivery

Primary outcomes

1

Description
Pain Intensity

Timepoint
First 24 hours after delivery (baseline value) - Seven days after the intervention - fourteen days after the intervention.

Method of measurement
Pain ruler

Secondary outcomes

1

Description
Stiffness

Timepoint
First 24 hours after childbirth, the postpartum seventh day, the fourteenth day after delivery

Method of measurement
Questionnaire

2

Description
Irritation

Timepoint
First 24 hours after childbirth, the postpartum seventh day, the fourteenth day after delivery

Method of measurement
### Questionnaire

#### Description
- Itching
- **Timepoint**
  - First 24 hours after childbirth, the postpartum seventh day, the fourteenth day after delivery
- **Method of measurement**
  - Questionnaire

#### Description
- Dryness
- **Timepoint**
  - First 24 hours after childbirth, the postpartum seventh day, the fourteenth day after delivery
- **Method of measurement**
  - Questionnaire

#### Description
- Discharge from the wound
- **Timepoint**
  - First 24 hours after childbirth, the postpartum seventh day, the fourteenth day after delivery
- **Method of measurement**
  - Questionnaire

#### Description
- Fever and chills
- **Timepoint**
  - First 24 hours after childbirth, the postpartum seventh day, the fourteenth day after delivery
- **Method of measurement**
  - Questionnaire

### Intervention groups

#### 1
- **Description**
  - Intervention group: phenytoin sodium, 1% Topical Cream. Once a day. Mothers were asked the night before sleep, after washing and drying the perineal area once a phalanx of ointment on the affected area is sutured so that it covers the particularity and after 1-2 minutes and do a clean pad and every 24 hours until the tenth day after delivery
- **Category**
  - Treatment - Drugs

#### 2
- **Description**
  - Intervention group: Honey cream, 30%. Once a day. Mothers were asked the night before sleep, after washing and drying the perineal area once a phalanx of ointment on the affected area is sutured so that it covers the particularity and after 1-2 minutes and do a clean pad and every 24 hours until the tenth day after delivery
- **Category**
  - Treatment - Drugs

### Recruitment centers

#### 1
- **Recruitment center**
  - Name of recruitment center
    - Kashan Tamin Ejtemaii Hospital (Doctor Shabih Khani)
  - **Full name of responsible person**
    - Mohadeseh lavvaf
  - **Street address**
    - Kashan Tamin Ejtemaii Hospital, next of Moavenat Darman, Shahid Beheshti Street, Kashan, Esfahan.
  - **City**
    - Kashan

### Sponsors / Funding sources

#### 1
- **Sponsor**
  - **Name of organization / entity**
    - Shahid Beheshti University of Medical Sciences
  - **Full name of responsible person**
    - Afshin Zarghi Doctor
  - **Street address**
    - Shahid Beheshti University of Medical Sciences, next of Taleghani Hospital, Shahid Aarabi Street, Yaman Sreet, Shahid Chamran Highway, Tehran.
  - **City**
    - Tehran
  - **Grant name**
    - **Grant code / Reference number**
    - **Is the source of funding the same sponsor organization/entity?**
      - Yes
    - **Title of funding source**
      - Shahid Beheshti University of Medical Sciences
  - **Proportion provided by this source**
    - 100
  - **Public or private sector**
    - empty
  - **Domestic or foreign origin**
    - empty
Person responsible for general inquiries

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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