Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Oct 2026

The effect of Rosemary cream on pain intensity and wound healing of episiotomy in nulliparous women

Protocol summary

Study aim
The effect of Rosemary cream on pain intensity and wound healing of episiotomy in nulliparous women

Design
Clinical trials with controlled, triple blind, randomized trials

Settings and conduct
This research will be carried in Motahari Hospital of Marvdasht on 92 nulliparous women with Natural vaginal delivery, including the criteria for entering the study on episiotomy . This is a triple-blind study. Researcher, patient and analyst will be blind. To randomly assign samples to each of the two intervention and control groups, four variable blocks are used.Then, in the intervention group, the rosemary cream and the control group from the placebo cream will be used for episiotomy

Participants/Inclusion and exclusion criteria
Inclusion criteria: nulliparous؛ Gestational age Between 37-42 weeks؛ The age of the mother Between 18-35 years old؛ Single baby؛ Cephalic؛ Natural vaginal delivery and Middle lateral episiotomy؛ Baby weight between 2500-4000 grams؛ No use effective medication for wound healing؛ Lack of amniotic membrane rupture for more than 12 hours؛ Not having midwifery problems at admission؛ exclusion criteria: Increased episiotomy؛ Hematoma in episiotomy after childbirth؛ Unwillingness to continue participating in the study؛ No used the correct cream؛ Mother's sensitivity to the Creams used in the study؛ Symptoms of infection in episiotomy؛ opened Episiotomy؛ Shoulder Dystopia

Intervention groups
In the intervention group, Rosemary cream is used twice a day until the tenth day after delivery on episiotomy ulcer. In the control group, placebo cream is also used in the same way

Main outcome variables
pain intensity and wound healing of episiotomy

General information

Reason for update
Enter the start and end dates of the completed sampling and the volume of the completed sample

Acronym

IRCT registration information
IRCT registration number: **IRCT20190308042971N1**
Registration date: **2019-08-24, 1398/06/02**
Registration timing: **prospective**

Last update: **2022-01-31, 1400/11/11**
Update count: **1**

Registration date
2019-08-24, 1398/06/02

Registrant information

Name
Fariba Mardani

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-21, 1398/04/30

Expected recruitment end date
2019-10-22, 1398/07/30

Actual recruitment start date
2019-09-01, 1398/06/10

Actual recruitment end date
2020-03-05, 1398/12/15

Trial completion date
2020-03-19, 1398/12/29

Scientific title
The effect of Rosemary cream on pain intensity and wound healing of episiotomy in nulliparous women

Public title
The effect of Rosemary cream on pain intensity and wound healing of episiotomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Inclusion criteria:Completion of informed consent form Gestational age Between 37-42 weeks The age of the mother Between 18-35 years old Single baby Cephalic Natural vaginal delivery and Middle lateral episiotomy Baby weight between 2500-4000 grams Iranian-Resident of Marvdasht city and The villages around it Minimum fifth grade primary education Mother in active phase of labor (dilatation 3-4 cm and regular uterine contractions)و BMI is 18/5-24/9 kg / m2 Mother lives with hers husband nulliparous

Exclusion criteria:
indication for cesarean section(Distress fetal, umbilical cord prolapse, diagnosis of the Tight pelvis by the doctor) having midwifery problems at admission(placenta previa،Polyhydramnios، Oligo Hydramnios) amniotic membrane rupture for more than 12 hours clear symptoms of perineal and vaginal infection at the time of admission anemia or thrombocytopenia having diabetes, anemia،Immune system disorders,... use effective medication for wound healing(Glucocorticoids, anticoagulants, immunosuppressants, chemotherapy, alcohol and benzodiazepines) use of drugs and tobacco anal lesions, Perineum or history of surgery on Perineum and cystocel and severe rectus

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **92**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
To randomly assign samples to each of the two intervention and control groups, four variable blocks are used. In this way, six of the possible blocks (BBAA, BABA, ABBA, BAAB AABB, ABAB) are first listed, and each one is assigned a number from one to six. Then, randomly, a number is selected from one to six, followed by individuals assigned to the test group (A) and control (B), based on the corresponding block. This will continue until the sample size is completed.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In order to blindness, the drugs prepared with codes A and B were prepared by the pharmacist's assistant, and only themselves knew about their content, the researcher and consultant of statistics and patients did not know the type of cream.

Placebo
Used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Gonabad University of Medical Sciences

Street address
Asian Roadside،Gonabad University of Medical Sciences

City
Gonabad

Province
Razavi Khorasan

Postal code
۹۶۹۱۷۹۳۷۱۸

Approval date
2018-12-03, 1397/09/12

Ethics committee reference number
IR.GMU.REC.1397.089

Health conditions studied

1

Description of health condition studied
episiotomy

ICD-10 code
O70.1

ICD-10 code description
Second degree perineal laceration during delivery

Primary outcomes

1

Description
wound healing of episiotomy

Timepoint
1-4-10 days after childbirth

Method of measurement

2

Description
pain intensity
Timepoint
1-4-10 days after childbirth
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Rosemary Cream 30 grams twice a day for 10 days (prepared at the Pharmacological Research Center of Mashhad Medicinal Plants) will be applied to the amount of a fingertip locally on the episiotomy site
Category
Treatment - Drugs

2

Description
Control group: Placebo cream 30 grams twice a day for 10 days (prepared at the Pharmacological Research Center of Mashhad Medicinal Plants) will be applied to the amount of a fingertip locally on the episiotomy site
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Motahari Hospital of Marvdasht
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gonabad 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
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Full name of responsible person
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Assistant Professor
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Only part of the data such as information about the main outcome or the like can be shared.
When the data will become available and for how long
6 months after printing the results
To whom data/document is available
Medical researchers
Under which criteria data/document could be used
Available at the reasonable request of researchers.
From where data/document is obtainable
Corresponding author of the published article
What processes are involved for a request to access data/document
Send email to the Corresponding author
Comments
