

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 71 4331 7002

Email address

mardani.f.stu@gmu.ac.ir

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), BMI is 18/5-24/9 kg / m²
Mother lives with her 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

9691793718

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

Fariba Mardani

Street address

Teacher's Street

City

Marvdasht

Province

Fars

Postal code

7371676711

Phone

+98 71 4334 2060

Fax

+98 71 4333 4935

Email

mardanif110@gmail.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Gonabad University of Medical Sciences

Full name of responsible person

Shahla Khosravan

Street address

Asian Roadside , Gonabad University of Medical Sciences

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Phone

+98 51 5722 3028

Fax

+98 51 5722 0578

Email

khosravan@gmu.ac.ir

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**

Gonabad University of Medical Sciences

Full name of responsible person

Fatemeh Hadizadeh Talasaz

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

Asian Roadside , Gonabad University of Medical Sciences

City

Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 517223028
Email
shahnazhadizadeh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Fatemeh Hadizadeh Talasaz
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Asian Roadside , Gonabad University of Medical Sciences
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 517223028
Email
shahnazhadizadeh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Fariba Mardani
Position
Master student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery

Street address
Asian Roadside , Gonabad University of Medical Sciences
City
Gonabad
Province
Razavi Khorasan
Postal code
9691793718
Phone
+98 51 5722 3028
Fax
Email
mardani.f.stu@gmu.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

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
