Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Evaluating the effect of Myrtus Communis cream on prineal healing and pain intensityof episiotomy in primiparous women

Protocol summary

Study aim
This study is conducted to determine the effect of topical cream on wound healing and episiotomy pain in primiparous women referred to the hospital of Amiralmomenin in Zabol city.

Design
Clinical trial, with control group, randomized, double blind

Settings and conduct
This study is done in Amiralmomenin hospital in Zabol city. The primiparus women that have inclusion criteria are randomized in two groups, control and intervention. Participants are fallowed up for 10 days. This study is double blind. The researcher and participants during the study not have any information about the type of creams.

Participants/Inclusion and exclusion criteria
primiparous women with mediolatral episiotomy who want to participate in the study. no allergy to Myrtus Communis cream. Attending at clinic for fallow up.

Intervention groups
The intervention group receives Myrtus Communis cream and control group receives placebo.

Main outcome variables
Better wound healling, Pain relief, reduce the risk of infection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180303038932N1**
Registration date: **2018-03-15, 1396/12/24**
Registration timing: **prospective**

Last update: **2018-03-15, 1396/12/24**
Update count: **0**

Registration date
2018-03-15, 1396/12/24

Registrant information
Name
fatemeh mirzaee
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-03-21, 1397/01/01

Expected recruitment end date
2018-06-20, 1397/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effect of Myrtus Communis cream on prineal healing and pain intensityof episiotomy in primiparous women

Public title
Evaluating the effect of Myrtus Communis cream on episiotomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All of the primiparus womens that have episiotomy

incision. Gestational age between 42-37 weeks Body mass index between 18.5-26. Having skill of reading and writing. Baby weight between 2500- 4000 g. Rupture of the membrane less than 24 hour. No hematoma in episiotomy incision area. No previous history of surgery and visible lesions in the perineal area. No manual placenta extraction . Single pregnancy with cephalic presentation.

Exclusion criteria:

Do not go to clinic on fallow up days Do not want to continue to participate in the study Do not regular use of the cream Have allergy against Myrtus Communis cream Having sex in the first five days after delivery Having remanipulation after repair episiotomy Having severe hemorrhage in first 24 hours after delivery

Age

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

Gender

Female

Phase

0

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is done by Excel software

Blinding (investigator's opinion)

Double blinded

Blinding description

Researcher and participants will be kept blind during the study and do not know which group receive drug and which receive placebo

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of medical sciences

Street address

Vali Asr St., Niayesh HW. Cross Section, Tehran, Tehran province, Iran

City

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Province

Tehran

Postal code

1985717443

Approval date

2017-10-09, 1396/07/17

Ethics committee reference number

IR.SBMU.PHNM.1396.847

Health conditions studied

1

Description of health condition studied

Episiotomy

ICD-10 code

O70

ICD-10 code description

Perineal laceration during delivery

Primary outcomes

1

Description

wound healing of episiotomy

Timepoint

At the beginning of the study and day 5,10 after starting the cream

Method of measurement

Improvement control form

2

Description

intensity of pain

Timepoint

At the beginning of the study and day 5,10 after starting the cream

Method of measurement

Measuring ruler pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Myrtus Communis cream, 10%, 5 mg, twice a day, for 10 day

Category

Treatment - Drugs

2

Description

Control group: Placebo cream, 10%, 5 mg, twice a day, for 10 day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amiralmomenin Ali Hospital
Full name of responsible person
Fatemeh Mirzaee
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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
Shahid Beheshti 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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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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