Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the effect of Olea and Alpha ointment on episiotomy wound healing in nulliparous women: a randomized double-blind placebo-controlled trial

Protocol summary

Study aim

Comparing the effect of Olea and Alpha ointment on episiotomy wound healing in nulliparous women

Design

A randomized double-blind placebo-controlled trial with a parallel design on 132 primiparous mothers (3 groups in each group of 44 participants with 15% probable loss. Phase 3, Randomization was done by Sealed Envelope Ltd. 2019 an online randomization service.

Settings and conduct

Eligible primiparous women refering to Al-Zahra hospital for delivery will be allocated into Olea, Alpha, and placebo ointment groups using blocked randomization. Data will be collected using the demographic questionnaire and REEDA scale. The first intervention in each group will be performed 4 hours after episiotomy. It will be advised each group to use a fingertip (2 g) of the ointment on the episiotomy wound after washing the hands and perineum, after 2 minutes to use a clean pad, and every 8 hours continue it until 10th day postpartum. The REEDA score will be calculated before the intervention, 24 hours after the intervention, 5th and 10th day after delivery.

Participants/Inclusion and exclusion criteria

Willingness and sign the written informed consent; Ability to read and write; Gestational age 37-42 weeks; primiparous; Singleton; Cephalic; Mediolateral episiotomy; Spontaneous placental delivery; Birth weight: 2500-4000 g; The 1st, 2nd, 3rd stages of labor less than 14 hours, 2 hours, 30 minutes; No perineal infection/lesion; No smoking/drug use/prenatal chronic disease: diabetes, cardiovascular, coagulation, hypertension; No prolonged ROM/ postpartum hemorrhage

Intervention groups

Olea ointment, Alpha ointment (intervention groups) and placebo ointment (control group)

Main outcome variables

Episiotomy wound healing score according to REEDA five components including (Redness, Edema, Ecchymosis, Discharge, Approximation) before the intervention, 24 hours after the intervention, 5th and 10th day after delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160630028717N3**
Registration date: **2022-04-28, 1401/02/08**
Registration timing: **prospective**

Last update: **2022-04-28, 1401/02/08**
Update count: **0**

Registration date

2022-04-28, 1401/02/08

Registrant information

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Parvaneh Rezasoltani
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-20, 1401/02/30

Expected recruitment end date
2022-09-21, 1401/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the effect of Olea and Alpha ointment on episiotomy wound healing in nulliparous women: a randomized double-blind placebo-controlled trial

Public title
Comparing the effect of Olea and Alpha ointment on episiotomy wound healing in nulliparous women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate to the study and sign a written informed consent form At least ability to read and write Gestational age 37 to 42 weeks (based on ultrasound or the first day of the last menstrual period) Primiparous Singleton pregnancy Cephalic presentation Mediolateral episiotomy Spontaneous placental delivery Birth weight between 2500 and 4000 grams The duration of the first, second and third stages of labor less than 14 hours, 2 hours, and 30 minutes, respectively
Exclusion criteria:
Having any visible infection and lesion in the perineum History of smoking and drug use History of chronic disease during pregnancy such as diabetes, cardiovascular and coagulation diseases, and high blood pressure Prolonged rupture of membranes Having postpartum hemorrhage
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **132**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, all eligible individuals will be equally allocated into three Olea, Alpha and placebo ointment groups by blocked randomization with a size of 6 blocks (by the statistical consultant of this project). Allocation of sample to groups will be done by online randomization service, Sealed Envelope Ltd and for allocation concealment will be used by Sequentially-Numbered, Opaque, Sealed Envelopes (SNOSE).
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be double blind and the participants and the investigator will be unaware of the content of ointment inside these packages. For blinding, the pharmacist colleague will pack the Olea, Alpha, and placebo ointments in the same shape and size opaque packages and tag the specific code based on random block allocation without the intervention and knowledge of the investigator. Then, these packages will be delivered to investigator. Investigator/student will allocate the participants in each one of the three groups based on inclusion criteria and blocked randomization and provide these packages to the participants for free of charge.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Guilan University of Medical Sciences
Street address
Deputy of Research and Technology of Gilan University of Medical Sciences, in front of 17 Shahrivar Hospital, Shahid Siadati Ave., Namjoo St.
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Guilan
Postal code
41446-66949
Approval date
2022-04-06, 1401/01/17
Ethics committee reference number
IR.GUMS.REC.1401.022

Health conditions studied

1

Description of health condition studied
Episiotomy wound healing
ICD-10 code
090.1
ICD-10 code description
Disruption of perineal obstetric wound

Primary outcomes

1

Description
Episiotomy wound healing score
Timepoint
Before starting the intervention, 24 hours after the first intervention, the fifth day , and tenth day after delivery
Method of measurement
REEDA Scale (Redness, Edema, Ecchymosis, Discharge, Approximation scale)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The Olea ointment will be considered as the intervention group. In this group, the first intervention will be performed 4 hours after the episiotomy by the mother in the presence of the researcher. After washing and drying the hands and perineal area, the mother will be advised to apply a fingertip (about 2 cm or 2 g) of the ointment to the episiotomy wound in the presence of the researcher, and after about 2 minutes use a clean sanitary pad and continue every 8 hours for up to 10 days. Olea ointment containing equal proportions of honey (33.4%), olive oil (33.3%) and sesame oil (33.3%) in 30 gram packages made by Isatis Shargh Farateb Research Scientific Company located in Yazd based on the relevant formula and will be provided to the researcher.
Category
Treatment - Drugs

2

Description
Intervention group: The Alpha ointment will be considered as the intervention group. In this group, the first intervention will be performed 4 hours after the episiotomy by the mother in the presence of the researcher. After washing and drying the hands and perineal area, the mother will be advised to apply a fingertip (about 2 cm or 2 g) of the ointment to the episiotomy wound in the presence of the researcher, and after about 2 minutes use a clean sanitary pad and continue every 8 hours for up to 10 days. Alpha ointment containing beeswax, flavonoids, unsaturated fatty acids and the active ingredient of henna and turmeric is currently made in 30 gram packages by Alpha Development Company in Iran and is available in pharmacies. This ointment will be purchased at the pharmacy.
Category
Treatment - Drugs

3

Description
Control group: The placebo ointment (same color and shape with the Olea and Alpha ointments) will be considered as the control group. In this group, the first intervention will be performed 4 hours after the episiotomy by the mother in the presence of the researcher. After washing and drying the hands and perineal area, the mother will be advised to apply a fingertip (about 2 cm or 2 g) of the ointment to the episiotomy wound in the presence of the researcher, and after about 2 minutes use a clean sanitary pad and continue every 8 hours for up to 10 days. The placebo ointment containing Vaseline with color, shape, smell and consistency similar to Olea ointment in 30 gram packages will be made and provided to the researcher by Isatis Shargh Farateb Research Scientific Company located in Yazd based on the relevant formula and will be provided to the researcher.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra educational, research, and remedial center
Full name of responsible person
seyed Fateme Mokhtari Sekandehi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research and Technology of Guilan University of Medical Sciences
Full name of responsible person
Mohammadreza Naghipour
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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
Vice Chancellor for Research and Technology of Guilan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Private

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
Shahid Beheshti School of Nursing and Midwifery
Full name of responsible person
Parvaneh Rezasoltani
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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

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

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

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the data and the main consequences will be shared after the study in format of knowledge translation and exchange report to the university, presentation of reports in domestic or foreign conferences and seminars and publication of article in domestic or foreign scientific-research journals.

When the data will become available and for how long

It is possible to access the study results after the defense and scientific confirmation of the dissertation In a 3 months period

To whom data/document is available

if requested, results will be available to other academic investigators and Vice Chancellor for Research and Technology of Guilan University of Medical Sciences

Under which criteria data/document could be used

The collected data is confidential and will not be disclosed to other persons without the awareness of the Vice Chancellor for Research and Technology of the relevant university

From where data/document is obtainable

To receive the documentation, send the email for update manager

What processes are involved for a request to access data/document

After the necessary checks, the desired documentary will be sent by email within one month period

Comments