Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Olea ointment and 2 % Lidocaine Gel on pain relieving and episiotomy wound healing in primiparous women

Protocol summary

Summary

This double-blind RCT will be conducted to determine and compare the effect of Olea ointment and Lidocaine gel 2% on pain and episiotomy wound healing in a sample of 123 primiparous women attending al-Zahra hospital, Rasht, Iran in 2017-2018. The samples will be firstly selected purposefully and then randomly allocated in one of the 3 groups: Olea (first intervention group), Lidocaine (second intervention group) and Normal Saline serum (routine care, control group). Inclusion criteria: Primiparous; 18-35y; voluntary participation; Live term pregnancy; single fetus; Cephalic presentation; Mediolateral episiotomy; Baby weight 2500-4000 g; Lack of PROM > 18 h; and maternal BMI = 19.8-30. Exclusion criteria: Unwillingness to participate; Inappropriate use of medications > 2 nights; Allergy to the medications; and failure to go to the hospital on days 5 and 10 postpartum. Four hours after episiotomy, the first intervention will be applied by the researcher. After that, the intervention groups will be asked to put some Olea ointment and Lidocaine gel on the sutures at bedtime and use a sanitary pad after 1-2 minutes, and then repeat it every 24 h till 10th day after childbirth. The intervention groups will also use routine care. The third group will only use Normal Saline twice a day. Pain and episiotomy wound healing will be investigated with Pain Visual Scale and REEDA scale respectively before intervention, 2h and 24 h after the first intervention, 5 and 10 days postpartum by the researcher. Data using descriptive and inferential statistics under SPSS 19 will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020332374N1**
Registration date: **2017-10-05, 1396/07/13**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2017-10-05, 1396/07/13

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Deputy of Research and Technology of Guilan University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Olea ointment and 2 % Lidocaine Gel on pain relieving and episiotomy wound healing in primiparous women

Public title

The effect of Olea ointment and Lidocaine Gel 2 % on pain relieving and episiotomy wound healing

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criterias: Iranian patients; Primiparous; 18-35 years old; Literate; Volunteer; Term pregnancy with single fetus; Cephalic presentation; Mediolateral episiotomy; Newborn weight about 2500-4000 g; Absence of diseases affecting wound healing; Lack of PROM longer than 18 hours; The maternal BMI range between 19/8 and 30. Exclusion criteria: Unwillingness to continue to participate in the study; The use of other effective drugs for wound healing during the study; Inappropriate use of medications (more than two nights); Allergy to the Olea ointment or Lidocaine gel 2%; Failure to go to hospital on days 5 and 10 after delivery; Having a sexual relationship in the first five days after childbirth.
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: **123**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Guilan University of Medical Sciences
Street address
Guilan University of Medical Sciences-Rasht-Iran
City
Rasht
Postal code
98
Approval date
2017-08-05, 1396/05/14
Ethics committee reference number
IR.GUMS.REC.1396.191

Health conditions studied

1

Description of health condition studied
Episiotomy
ICD-10 code
O70.0, O70
ICD-10 code description
First degree perineal laceration during delivery,Second degree perineal laceration during delivery

Primary outcomes

1

Description
Severity of episiotomy pain
Timepoint
Before intervention; 2 h and 24 h after first intervention; 5th and 10th days of postpartum
Method of measurement
pain visual scale

2

Description
Episiotomy wound healing
Timepoint
Before intervention; 2 h and 24 h after first intervention; 5th and 10th days of postpartum
Method of measurement
REEDA Scale

Secondary outcomes

1

Description
Drug side effects
Timepoint
2h after first intervention; 24h after first intervention; 5th and 10th days of postpartum
Method of measurement
Drug side effects Form

2

Description
Maternal health condition
Timepoint
2h after first intervention; 24h after first intervention; 5th and 10th days of postpartum
Method of measurement
Maternal health condition Form

3

Description
Used analgesic
Timepoint
2h after first intervention; 24h after first intervention; 5th

and 10th days of postpartum

Method of measurement

Used analgesic Form

Intervention groups

1

Description

Olea Ointment (First intervention group): This ointment is made in Farateb Company, Yazd,Iran. Its ingredients are:10 g Olive Oil, 10g Sesame, and 10 g honey.This ointment is available in 30 gram tubes.Four hours after episiotomy, the first intervention will be applied by the researcher. After that, the intervention groups will be asked to put some Olea ointment on the sutures at bedtime and use a sanitary pad after 1-2 minutes, and then repeat it every 24 h till 10th day after childbirth.

Category

Treatment - Drugs

2

Description

Lidocaine gel 2% (Second intervention Group) is made in Razi Drug Company, Tehran, Iran. Four hours after episiotomy, the first intervention will be applied by the researcher. After that, the intervention groups will be asked to put some Lidocaine gel 2% on the sutures at bedtime and use a sanitary pad after 1-2 minutes, and then repeat it every 24 h till 10th day after childbirth. Both intervention groups will also use routine care (use of Normal Saline twice a day).

Category

Treatment - Drugs

3

Description

Normal Saline 0.9 % (Control Group), non-injectable, made in Parsdaro Co, Tehran,Iran. The Control group will only use Normal Saline twice a day till 10th day after childbirth.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Dr.Fatemeh Jafarzadeh-Kenarsari

Street address

Rasht-Guilan-Iran

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Deputy of Research and Technology

Street address

Infront of 17 Sharivar Hospital-Rasht-Guilan-Iran

City

Rasht

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Guilan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

GUILAN UNIVERSITY OF MEDICAL SCIENCES

Full name of responsible person

Dr. FATEMEH JAFARZADEH-KENARSARI

Position

Assistant professor

Other areas of specialty/work

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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