Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of olive leaf extract ointment on pain intensity and healing wound of episiotomy in Primiparous women

Protocol summary

Summary

The purpose of this study is evaluating the effect of Olive leaf extract ointment on pain intensity and healing wound of episiotomy. This randomize clinical trial will done on 90 primiparous women who admitted in Shiraz Hafez and Hazrat Zeinab hospital (With Inclusion criteria contain: Age between 17 to 35 years, Age between 17 to 35 years; Primiparous women; Normal vaginal delivery; Full term singleton pregnancy with cephalic presentation; Gestational age between 37 to 42 weeks; Medio-lateral episiotomy without extending the incision and tear of grade 3 and 4; Body mass index <30; Absence of reconstructive surgery in the perineal area; Absence of illness, Not using drugs effecting on wound healing , Exclusion criteria: Failure to use the correct and consistent command of ointment; Abnormal vaginal bleeding after delivery; Postpartum perineal manipulation; Episiotomy infection; The need for episiotomy stitches this location; Sensitivity to ointments). Eligible women will be allocated to three the prevention and control groups with block randomization. Ointments (Olive and placebo made by pharmaceutical industries Dana Kasian Lorestan) will be used 3 times a day and for 10 days with amount of one knuckle (1 gram) by mother. In the control group 10% betadine solution of 3 tablespoons in 4 glasses of water , 3 times a day for 10 days will be used for sitz bath . Pain intensity and Healing of episiotomy in 5 innings (1,3,7,10,14 days) after episiotomy will evaluated.

General information

Acronym

Ointment Pain Episiotomy Shiraz

IRCT registration information

IRCT registration number: **IRCT2015062422908N1**
Registration date: **2015-08-02, 1394/05/11**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2015-08-02, 1394/05/11

Registrant information

Name
Sara Sepasi
Name of organization / entity
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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stud2280234432@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-05-04, 1394/02/14

Expected recruitment end date

2015-08-05, 1394/05/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of olive leaf extract ointment on pain intensity and healing wound of episiotomy in Primiparous women

Public title

Effect of olive leaf extract ointment on pain intensity and healing wound of episiotomy

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria contain: Age between 17 to 35 years, Age between 17 to 35 years; Primiparous women; Normal vaginal delivery; Full term singleton pregnancy with cephalic presentation; Gestational age between 37 to 42 weeks; Medio-lateral episiotomy without extending the incision and tear of grade 3 and 4; Body mass index <30; Absence of reconstructive surgery in the perineal area; Absence of illness, Not using drugs effecting on wound healing . Exclusion criteria: Failure to use the correct and consistent command of ointment; Abnormal vaginal bleeding after delivery; Postpartum perineal manipulation; Episiotomy infection; The need for episiotomy stitches this location; Sensitivity to ointments .

Age
From **17 years** old to **35 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic commity of shiraz university of medical sciences

Street address
Zand street Shiraz

City
Shiraz

Postal code
71345-1978

Approval date
2010-08-20, 1389/05/29

Ethics committee reference number
94-7472

Health conditions studied

1

Description of health condition studied
episiotomy

ICD-10 code
O90.1

ICD-10 code description
Disruption of perineal obstetric wound

Primary outcomes

1

Description
Pain intensity

Timepoint
4 hours after delivery (first day after delivery) ,3 days after delivery,7 days after delivery, 10 days after delivery,14 days after delivery.

Method of measurement
Visual Analouge Scale

2

Description
Healing of episiotomy

Timepoint
4 hours after delivery (first day after delivery) ,3 days after delivery,7 days after delivery, 10 days after delivery,14 days after delivery.

Method of measurement
REEDA scale

Secondary outcomes

empty

Intervention groups

1

Description
The intervention group: Olive leaf extract ointment 3 times a day for 10 days (preparation and packaging by Dana kasian Khorram Abad company) as much as one finger (equivalent to 1 gram) will be used locally on the episiotomy .

Category
Treatment - Drugs

2

Description
The placebo group: Placebo ointment 3 times a day for 10 days (preparation and packaging by Dana kasian Khorram Abad company) as much as one finger (equivalent to 1 gram) will be used locally on the episiotomy .

Category
Placebo

3

Description
Control group: 10% betadine solution of 3 tablespoons in 4 glasses of water , 3 times a day for 10 days will be used for sitz bath.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Zainab Hospital Shiraz
Full name of responsible person
Sara Sepasi
Street address
Shiraz Valiasr street
City
Shiraz

2

Recruitment center
Name of recruitment center
Hafez Hospital Shiraz
Full name of responsible person
Sara Sepasi
Street address
Shiraz Chamran Boulevard
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Basir Hashemi
Street address
7th Floor, Shiraz University of Medical Sciences, Zand street
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Scienses
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Maasumeh Kaviani
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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