

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3823 2764

###### Email address

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

Shiraz

## 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 Sciences

##### Full name of responsible person

Maasumeh Kaviani

##### Position

Master's degree in Midwifery, Faculty member

##### Other areas of specialty/work

##### Street address

Shiraz Zand street

##### City

Shiraz

##### Postal code

##### Phone

+98 71 3647 4251

##### Fax

##### Email

kavianimaasumeh@yahoo.com kavianm@sums.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

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## Person responsible for updating data

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**Web page address**

**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*