

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### The Effect of Olive Cream on Pain Intensity and Cesarean Section Wound Healing among Women

#### Protocol summary

##### Study aim

The effect of olive cream on pain intensity and cesarean section in women

##### Design

semi-experimental design with the control group, the sample size will be 108 patients. Each group consists of 36 people.

##### Settings and conduct

This is a quasi-experimental design that will be performed on 108 women who have a cesarean section and who are referred to Arak Taleghani Hospital, Arak University of Medical Sciences, Arak, Iran. Sampling will be done by the available method. Random blocking will be done in the form of four blocks and women will randomly be divided into three groups: olive cream (n = 36), placebo group (n = 36) and the control group (n = 36). The intervention group will use the olive cream twice a day from the second day of surgery until the tenth day after surgery, and the placebo group, which has a cream-like olive cream in terms of color and odor and appearance, like the olive cream and from day two to day 10, it will be used twice daily and the control group will receive routine care after surgery. Assessing the severity of pain and wound healing on days 2 and 10 will be done by the researcher using the Visual Analogue Scale (VAS). The duration of surgical wound healing from the onset of the study to 10 days after surgery will be calculated and will be compared in three groups.

##### Participants/Inclusion and exclusion criteria

Inclusion and exclusion criteria: Term pregnancy with BMI less than 30 and undergo cesarean section for the first or second time. If there is any disease or drug-related to wound healing, the sample will be excluded.

##### Intervention groups

Intervention group: use olive cream twice a day from the second day after cesarean to 10 days. Placebo group: Use placebo 2 times a day from the second day after cesarean section to 10 days. Control group: only routine post-operative care.

#### Main outcome variables

Pain Intensity : Wound Healing

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180427039436N6**

Registration date: **2019-12-20, 1398/09/29**

Registration timing: **prospective**

Last update: **2019-12-20, 1398/09/29**

Update count: **0**

##### Registration date

2019-12-20, 1398/09/29

##### Registrant information

##### Name

Leila Amiri Farahani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4365 1139

##### Email address

l.amirifarahani@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-20, 1398/12/01

##### Expected recruitment end date

2020-09-21, 1399/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The Effect of Olive Cream on Pain Intensity and Cesarean Section Wound Healing among Women

**Public title**

The Effect of Olive Cream on Pain Intensity and Cesarean Section Wound Healing among Women

**Purpose**

Health service research

**Inclusion/Exclusion criteria****Inclusion criteria:**

Being Iranian gestational age between 37 and 42 complete weeks BMI less than 30 No history of cesarean section more than twice

**Exclusion criteria:**

chorioamnionitis history of known diseases or drugs disrupting wound healing Occurrence of any abnormalities that result in hospitalization of the neonatal intensive care unit (NICU) excessive bleeding and the need for blood transfusion Hysterectomy or myomectomy Simultaneously with cesarean section smoking or drug abuse Prolonged rupture (more than 18 hours) of pre-operative amniotic fluid sac

**Age**

No age limit

**Gender**

Female

**Phase**

3

**Groups that have been masked**

No information

**Sample size**

Target sample size: **108**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, a quadratic block randomization method will be used. Randomization tool is statistical software.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee Of Iran University of Medical Sciences

**Street address**

Hemat Highway next to Milad Tower, Tehran

**City**

tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2019-09-24, 1398/07/02

**Ethics committee reference number**

IR.IUMS.REC.1398.651

**Health conditions studied****1****Description of health condition studied**

cesarean section

**ICD-10 code**

o82

**ICD-10 code description**

Single delivery by caesarean section

**Primary outcomes****1****Description**

wound healing

**Timepoint**

2 days after cesarean section and 10 days after cesarean section

**Method of measurement**

REEDA Scale

**2****Description**

Pain Intensity

**Timepoint**

2 days after cesarean section and 10 days after cesarean section

**Method of measurement**

VAS scale (visual analogue scale)

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: From the mothers of the intervention group who meet for the first time 2 hours after surgery, they will be asked to use 2 times oil creams at the site of the caesarean wound from day 2 after cesarean section until 10 days after surgery.

**Category**

Other

## 2

### Description

Intervention group: The mothers in the placebo group will use a placebo twice a day after the second day of surgery, until the 10th day. A placebo that looks like a cream similar to the olive cream.

### Category

Placebo

## 3

### Description

Control group: The control group received neither local honey nor any of the local disinfectant materials (such as povidone iodine). The control group will receive routine postoperative care only.

### Category

Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani Hospital

##### Full name of responsible person

mahdiyeh taheri

##### Street address

Arak, the western side of Imam Khomeini Street next to the gas company, Taleghani Educational Center

##### City

arak

##### Province

Markazi

##### Postal code

3816149369

##### Phone

+98 86 3277 6065

##### Email

lt-taleghani@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Iran University of Medical Sciences

##### Street address

Shahid Hemmat highway, District 2

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۴۹۶۱۴۵۳۵

##### Phone

+98 21 6650 9024

##### Fax

+98 21 6650 9024

##### Email

malakoutik@yahoo.com

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Iran 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

Iran University of Medical Sciences

##### Full name of responsible person

Mahdiye Taheri

##### Position

student

##### Latest degree

Master

##### Other areas of specialty/work

Midwifery

##### Street address

Rashid Yasemi st

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Tehran

##### Province

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1996713883

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taheri.mh1995@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

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##### Full name of responsible person

Mahdiye Taheri

##### Position

student

##### Latest degree

Master

##### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Leila Amiri Farahani  
**Position**  
Assistant professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Reproductive Health  
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1996713883  
**Phone**  
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**Email**  
l.amirifarahani@gmail.com

## 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

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available