

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### The effect of the ointment of Sesamum on the intensity of episiotomy pain and wound healing

#### Protocol summary

##### Study aim

evaluate the effect of sesame ointment on pain intensity of episiotomy and wound healing

##### Design

the study population consisted of women admitted to Akbar Abadi maternity hospital admitted for normal birth. The research sample consisted of 104 primiparous women who were randomly assigned to quadruple blocks.

##### Settings and conduct

Evaluation of healing of episiotomy and pain intensity before, 7 and 10 days after intervention was done by a trained researcher and recorded in the form of healing wound of REEDA and pain form VAS. Ointments are packed in the same color and aroma with the same codes as A, B and will be placed on samples according to the letters inserted in the form of the drug form.

##### Participants/Inclusion and exclusion criteria

Age 18-35; gestational age 42-37 weeks; lack of addiction and psychotropic drug; single cephalic fetus; no history of damage or previous surgery and visible lesions in the perineum; lack of rectocele and severe cystosclerosis grade 2; anesthesia with lidocaine 1%; episiotomy incision 45° and medial; lack of vaginal symptom inflammation; having BMI lower than 30; no coagulation; connective tissue disorders; diabetes; Anemia; immune deficiency; malnutrition; no amniotic rupture for more than 24 hours; lack of long or fast delivery; having separate sutures restored with CutCuteCotton. fever; hemmatoma; abnormal vaginal bleeding; Postpartum curettage

##### Intervention groups

intervention group (sesame ointment) and control group (placebo) use ointments every 8 hours for 10 days.

##### Main outcome variables

pain intensity is different before and 7 days after treatment with sesame ointment and placebo; pain intensity 7 and 10 days after treatment with sesame

ointment and placebo; the wound healing before and 7 days after treatment is different from treatment with sesame ointment in placebo; The wound healing of episiotomy 7 and 10 days is different from treatment with sesame ointment in placebo.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170112031902N2**

Registration date: **2018-04-09, 1397/01/20**

Registration timing: **retrospective**

Last update: **2018-04-09, 1397/01/20**

Update count: **0**

##### Registration date

2018-04-09, 1397/01/20

##### Registrant information

##### Name

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 91208360111

##### Email address

najmeseven@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-11-22, 1396/09/01

##### Expected recruitment end date

2018-03-21, 1397/01/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of the ointment of Sesamum on the intensity of episiotomy pain and wound healing

**Public title**

The effect of the ointment of Sesamum on the episiotomy wound

**Purpose**

Treatment

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

Age of 18 to 35 years old gestational age of 42-37 weeks lack of susceptibility to certain drugs in the past living with a spouse lack of addiction and psychotropic drugs lack of history of hepatocellular disorders single fetus with cephalic presentation no history of damage Or previous surgery and visible lesions in the perineum lack of rectocele and severe cystosclerosis grade 2 and upper wall or mass in the vaginaperineal anesthesia with lidocaine 1% perineal anesthesia with lidocaine 1% episiotomy incision 45 ° and medial lateral lack of vaginal symptom inflammation At the onset of the study having no BMI greater than 30 no coagulation and connective tissue disorders, diabetes Anemia, immune deficiency, malnutrition no amniotic rupture for more than 24 hours lack of long or fast delivery having separate sutures that have been restored with Cut Cute Cotton.

**Exclusion criteria:**

presence of a fever Hematoma formation Perform curettage action Abnormal vaginal bleeding

**Age**

No age limit

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **104**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

By random allocation method, blocked in one of the intervention and control groups by random block method with two patients.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

In order to blind the study, the research and statistical

analysis group and mothers will not be aware of the type of ointment used.

**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**

Tehran, Hemat Highway next to Milad Tower, Iran University of Medical Sciences

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۳۹۶۱۴۵۳۵

**Approval date**

2017-12-03, 1396/09/12

**Ethics committee reference number**

IR.IUMS.REC 1396.9311373003

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

episiotomy

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Severity of pain in episiotomy

**Timepoint**

Before, 7 and 10 days after intervention

**Method of measurement**

Visual Analog Scale (VAS)

**2****Description**

Healing episiotomy

**Timepoint**

Before, 7 and 10 days after intervention

**Method of measurement**

REEDA tool

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In this study, the sesame oil ointment brand Burnagol, a pharmaceutical company of Gol-Dara, was approved by the Food and Drug Administration of Iran, with beta-cytosterol at 0.25% as the main ingredient in the trace element of sesame oil. Four hours after episiotomy repair, use a cuff (equivalent to 25 mg) of ointment on episiotomy location every 8 hours for ten days.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: In this study, the placebo ointment in Shahid Beheshti Pharmaceutical Faculty was created at the faculty laboratory with the same amount, shape, odor, color and tube similar to the intervention drug, the main basis of which is vaseline (other materials are neutral compounds). It should be noted that the base of each ointment is one, so there is no need for another control group.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Akbar Abadi Hospital

##### Full name of responsible person

Najme Amani Babadi

##### Street address

Tehran, Hemat Highway next to Milad Tower, Iran  
University of Medical Sciences

##### City

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##### Province

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+98 21 86701

##### Email

najmeseven@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Iran University of Medical Sciences

#### Full name of responsible person

Dr Masoome Kheirkhah

#### Street address

Valis Asr Street, Above Vanak Square, Rashidiassemi  
Avenue, Iran Nursing and Midwifery Faculty

#### City

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#### Province

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#### Phone

+98 21 86701

#### Email

najmeseven@gmail.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

Najme Amani Babadi

##### Position

Student of Master of Midwifery

##### Latest degree

Bachelor

##### Other areas of specialty/work

Midwifery

##### Street address

Valis Asr Street, Above Vanak Square, Rashidiassemi  
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##### Province

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##### Email

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Masoome Kheirkhah

**Position**

Associate professor

**Latest degree**

Ph.D.

**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**

Najme Amani Babadi

**Position**

student of master of midwifery

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Tehran, Valiasr St., above Vanak Square,  
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**Email**

najmeseven@gmail.com

**Web page address**

## 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

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

Yes - There is a plan to make this available

### Data Dictionary

Not applicable

### Title and more details about the data/document

Potential data can be shared after unidentifiable people

### When the data will become available and for how long

The start of the access period is 6 months after the results are printed

### To whom data/document is available

Data will only be available to researchers in academia and academia

### Under which criteria data/document could be used

I do not have any plans yet

### From where data/document is obtainable

Najme Amani Babadi Faculty of Nursing and Midwifery,  
Iran University of Medical Sciences Phone Call email:  
najmeseven@gmail.com

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

A week after sending or sending an email, information is sent.

### Comments