

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Evaluating the effect of Frankincense Ointment on pain intensity and improving Episiotomy injury in primiparous women

#### Protocol summary

##### Study aim

Evaluating the effect of Frankincense ointment on pain intensity and improving Episiotomy injury

##### Design

A clinical trial with a control group, with a parallel, triple blind, randomized clinical trial

##### Settings and conduct

Research in Mehdiye Shoosh hospital will be performed on episiotomy ulcer. This is a triple blind study, and the researcher, patient, and analyst will be blind

##### Participants/Inclusion and exclusion criteria

age18-35 years

##### Intervention groups

In the intervention group, the Frankincense ointment was used on episiotomy ulcers on days 1-5-10 postpartum. In the control group, ointment containing vaseline was also used in the same way.

##### Main outcome variables

reada score Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190110042320N1**

Registration date: **2019-03-09, 1397/12/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-03-09, 1397/12/18**

Update count: **0**

##### Registration date

2019-03-09, 1397/12/18

##### Registrant information

##### Name

Elham laki

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8877 0061

##### Email address

elham.laki@sbmu.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2019-01-10, 1397/10/20

##### Expected recruitment end date

2019-04-21, 1398/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the effect of Frankincense Ointment on pain intensity and improving Episiotomy injury in primiparous women

##### Public title

The effect of Frankincense Ointment on pain intensity and improving Episiotomy injury

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

Age 18 - 35 years Not having any hazardous background (Anemia, Infection, Diabetes and Etc Be Primiparous Gestational age 37 - 42 weak Cephalic Single baby and alive Non-instrumental vaginal delivery with mediolateral episiotomy Exit spontaneously of placenta Maternal BMI between 19 / 8 - 26 Normal process of labor(In accordance with the plotogram chart) Rupture of the bag under 18 hours

**Exclusion criteria:****Age**

From **18 years** old to **35 years** old

**Gender**

Female

**Phase**

2-3

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**Sample size**

Target sample size: **116**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples are in accordance with a randomized pre-set table , Were placed in one of the intervention or control groups.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

For the purpose of blindness, the drugs prepared with codes A and B that were prepared by a pharmacist of the project and The researcher and consultant of statistics and patients did not know the type of Ointment.

**Placebo**

Used

**Assignment**

Other

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

empty

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

Ethics commitee of Shahid beheshti university of medical sciences

**Street address**

Valiasr Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Approval date**

2017-10-09, 1396/07/17

**Ethics committee reference number**

IR.SBMU.PHNM.13960848

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

Episiotomy

**ICD-10 code**

O70.1

**ICD-10 code description**

Second degree perineal laceration during delivery

**2****Description of health condition studied**

Postpartum pain

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

Healing Episiotomy location

**Timepoint**

on 1-5-10 day of postpartum

**Method of measurement**

Perineal Improvement Assessment Scale( REEDA )

**2****Description**

Intensity of pain

**Timepoint**

on 1-5-10 day of postpartum

**Method of measurement**

Visual Analogue Scale

**Secondary outcomes****1****Description**

Episiotomy wound healing

**Timepoint**

On days 1, 5 and 10 after delivery

**Method of measurement**

Perineal Wound Healing Score (REEDA)

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

Therapeutic intervention group: Extract of Ointment Extract 2 times a day for 10 days (prepared and packed by the Faculty of Pharmacy of Shahid Beheshti University) at a rate of one finger (equivalent to one gram) will be applied locally to episiotomy.

**Category**

Treatment - Drugs

## 2

### Description

Control group: placebo Ointment Extract 2 times a day for 10 days (prepared and packed by the Faculty of Pharmacy of Shahid Beheshti University) at a rate of one finger (equivalent to one gram) will be applied locally to episiotomy.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Mahdiyeh Hospital

**Full name of responsible person**

Shahnaz Tork Zahrani

**Street address**

Valiasr ave

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#### Recruitment center

**Name of recruitment center**

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### 3

#### Recruitment center

**Name of recruitment center**

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**Full name of responsible person**

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr. Shahnaz Tork Zahrani

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Velynjak Ave., Chamran Highway, Shahid Beheshti University of Medical Sciences

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**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Elham laki

**Position**

Masters student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Position**

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Ph.D.

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**Person responsible for updating data****Contact****Name of organization / entity**

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**Position**

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**Other areas of specialty/work**

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**Email**

Elham.laki@sbm.ac.ir

**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**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available