

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

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8820 2521

Email

zahranishahnaz@yahoo.com

2

Recruitment center

Name of recruitment center

Mahdiye hospital

Full name of responsible person

Shahnaz Tork Zahrani

Street address

Valiasre ave

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8820 2521

Email

zahranishahnaz@yahoo.com

3

Recruitment center

Name of recruitment center

Mahdiye Hospital

Full name of responsible person

Shahnaz tork zahrani

Street address

valiasr ave

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8820 2521

Email

zahranishahnaz@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Shahnaz Tork Zahrani

Street address

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

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8820 2521

Email

zahranishahnaz@yahoo.com

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

Street address

Valiasr ave

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8820 2521

Email

Elham.laki70@gmail.com

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shahnaz tork zahrani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

Street address

valiasr ave

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

zahranihashnaz@yahoo.com

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Elham Laki

Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Valiasr St. Al-Zahra dormitory

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8820 2521

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