

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of topical ointment of Propolis on severity of episiotomy pain and wound healing: a randomized controlled trial

Protocol summary

Study aim

Determining the effect of propolis on severity of episiotomy pain and wound healing

Design

A three-blind controlled randomized controlled clinical trial, 72 women with 1 and 2 pregnancies will be assigned to one of the intervention and control groups with a ratio of 1:1, using a purpose-based sampling method.

Settings and conduct

People will be selected from Alzahra and Taleghani hospitals. Stratification will be done based on first and second birth. Ointments of both groups will be completely similar in appearance. In addition to the person determining the sequence of placement of people in the groups, the only person who will know the type of drug prescribed will be the research assistant, and the participants, researcher, data collectors and analysts will not be informed.

Participants/Inclusion and exclusion criteria

Entry requirements: gravid one and two, living in Tabriz city, willingness and possibility of mother's referral to Alzahra and Taleghani hospitals on the 10th day and vaginal delivery with mediolateral incision; Conditions of non-entry: prolonged rupture of the amniotic sac, certain drugs using, alcohol or drug addiction, history of diseases interfering with wound healing, abnormal postpartum bleeding, preterm labor, allergy to Propolis, large or extended episiotomy, history of surgery or visible lesions in the perineum, severe anemia, other tears besides episiotomy, non-continuance of cooperation, incomplete participation

Intervention groups

The intervention group will use 2 centimeter of Propolis ointment 2 times a day with an interval of 12 hours and the control group will use placebo ointment 2 times a day with an interval of 12 hours for a length of 2 centimeter for 10 days.

Main outcome variables

Pain level and wound healing of episiotomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110524006582N37**

Registration date: **2023-03-09, 1401/12/18**

Registration timing: **prospective**

Last update: **2023-03-09, 1401/12/18**

Update count: **0**

Registration date

2023-03-09, 1401/12/18

Registrant information

Name

Mahin Kamalifard

Name of organization / entity

Tabriz University of Medical Sciences and Health Services

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-13, 1401/12/22

Expected recruitment end date

2024-03-12, 1402/12/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of topical ointment of Propolis on severity of episiotomy pain and wound healing: a randomized controlled trial

Public title
The effect of topical ointment of Propolis on severity of episiotomy pain and wound healing

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Gravid one and two women Living in Tabriz city
Willingness and possibility of the mother to go to Alzahra and Taleghani hospitals on the 10th day Vaginal delivery with mediolateral incision
Exclusion criteria:
Prolonged rupture of the amniotic sac (more than 18 hours) Use of special drugs such as anti-inflammatory and anticoagulant drugs Addiction to alcohol or drugs History of diseases interfering with wound healing such as systemic, cardiac, renal, pulmonary diseases, coagulation disorder, immunodeficiency, connective tissue disorder, diabetes, anemia, mental illness, hemophilia (based on medical records) Abnormal postpartum bleeding Preterm labor Allergy to propolis Large or extended episiotomy (third or fourth degree tear and episiotomy cut length greater than 3-4 cm) History of surgery or visible lesions in the perineum Severe anemia (hemoglobin less than 7 grams per deciliter) Other tears in addition to episiotomy, such as urethral tears Non-continuing cooperation of participants Incomplete participation that is not possible to achieve results

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: 72

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling will be done based on the purpose, the sequence of allocation in the intervention groups will be using a computer randomization program and with an allocation ratio of 1:1. In order to hide the allocation (allocation concealment), the type of ointment for each participant (drug or placebo) will be determined by a person not involved in the study using a randomizer, and

a numbered label will be placed on the ointments.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Participants, researcher and data analyst will be blinded. Both drug and placebo will be completely similar in terms of color, size and shape and will be presented in similar packages. In addition to the person determining the sequence of placement of people in the groups, the only person who will know the type of drug prescribed will be the research assistant, and the participants, researcher, data collectors and analysts will not be informed.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee of Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz university of medical science, Azadi avenue

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2023-01-28, 1401/11/08

Ethics committee reference number

IR.TBZMED.REC.1401.971

Health conditions studied

1

Description of health condition studied

Severity of episiotomy pain

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Episiotomy wound healing

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain level of episiotomy

Timepoint

At the beginning of the study (before the start of the intervention) and on the 10th day after delivery

Method of measurement

Visual Analogue Scale

2

Description

Episiotomy wound healing rate

Timepoint

At the beginning of the study (before the start of the intervention) and on the 10th day after delivery

Method of measurement

Redness, Edema, Ecchymosis, Discharge, Approximation scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Participants in the intervention group will use 2 cm (1 knuckle length) ointment on the episiotomy site twice a day, 12 hours apart, for ten days. The contents of the ointment will include Propolis and Oserin (Vaseline and a little Lanolin). Propolis will be made from Royal Shahd Pirlanta bee products company, which is a beehive breeding place in Azerbaijan region, and Oserin will be made from Dr. Shahtalebi cosmetic company.

Category

Treatment - Other

2

Description

Control group: Participants in the control group will use 2 cm (1 knuckle length) ointment on the episiotomy site 2 times a day, 12 hours apart, for ten days. The prepared ointment base will be used as a placebo ointment without Propolis. If there is a need to adjust the color of the ointment, the approved pharmaceutical color will be used to match the color of the placebo and Propolis ointment.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Masoomeh Rafat Nia

Street address

School of Nursing and Midwifery, Shariati street

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2

Recruitment center

Name of recruitment center

Taleghani Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name
Grant code / Reference number
70312
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
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Masoomah Rafat Nia
Position
Student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participants data is confidential.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available