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

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Iran (Islamic Republic of)

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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
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School of Nursing and Midwifery, ۹ Shariati street
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
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
Full name of responsible person
Masoomeh 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