# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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
**Street address**
School of Nursing and Midwifery, ۹ Shariati street
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### 2

**Recruitment center**
**Name of recruitment center**
Taleghani Hospital
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## Sponsors / Funding sources

### 1

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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**
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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