# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Evaluation of the Effects of Topical Phenytoin and Oral Bromelain on Episiotomy Wound Healing Progress and Pain Reduction in Primiparous Women: A Randomized Controlled Trial.

## Protocol summary


**Study aim**
To compare topical phenytoin, oral Anahil, and their combination versus placebo for episiotomy pain and healing.

**Design**
A double-blind, placebo-controlled randomized trial of 136 women in four groups.

**Settings and conduct**
This study will be conducted at Fatemieh Teaching Hospital in Hamadan, Iran, involving 136 primiparous women following vaginal delivery with episiotomy. Participants will be allocated to four groups: placebo, oral Anahil, topical 1% phenytoin, and combined treatment for 14 days. Pain will be assessed using VAS and wound healing using REEDA by a blinded assessor..

**Participants/Inclusion and exclusion criteria**
Inclusion: Primiparous women aged 18–40 with BMI 19–26, singleton pregnancy, vaginal delivery with mediolateral episiotomy, no major diseases or wound-healing medications, and written consent. Exclusion: Severe complications, instrumental delivery, wound infection, drug allergy, non-adherence over 20%, interacting medications, or withdrawal.

**Intervention groups**
Group 1 – Control: Standard care, placebo capsules and cream for 14 days. Group 2 – Anahil: Standard care, oral Anahil 500 mg every 12 hours and placebo cream for 14 days. Group 3 – Phenytoin: Standard care, topical phenytoin 1% twice daily and placebo capsules for 14 days. Group 4 – Combined: Standard care, oral Anahil 500 mg every 12 hours and topical phenytoin 1% twice daily for 14 days.

**Main outcome variables**
Episiotomy pain (VAS); episiotomy wound healing (REEDA).


## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20261008071352N1**
Registration date: **2026-10-16, 1405/07/24**
Registration timing: **prospective**

Last update: **2026-10-16, 1405/07/24**
Update count: **0**

**Registration date**
2026-10-16, 1405/07/24

**Registrant information**


**Name**
Leila Torkashvand
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**Recruitment status**
**Not yet recruiting**

**Funding source**

**Expected recruitment start date**
2026-11-21, 1405/08/30

**Expected recruitment end date**
2027-03-19, 1405/12/28

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**

Evaluation of the Effects of Topical Phenytoin and Oral Bromelain on Episiotomy Wound Healing Progress and Pain Reduction in Primiparous Women: A Randomized Controlled Trial.

**Public title**

Evaluation of the effects of topical phenytoin and oral bromelain on wound healing and pain reduction following episiotomy

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Women aged 18–40 years body mass index (BMI) of 19–26 kg/m² singleton pregnancy primiparity who undergo vaginal delivery with a mediolateral episiotomy absence of significant underlying medical conditions (including diabetes mellitus, gestational hypertension, coagulation disorders, and hepatic or renal diseases) no use of medications that may affect wound healing (such as corticosteroids and immunosuppressive agents) willingness to participate in the study and provision of written informed consent

**Exclusion criteria:**

Occurrence of severe obstetric complications (such as severe hemorrhage or uterine rupture) instrumental delivery signs of wound infection at baseline a history of hypersensitivity to the study medications non-adherence to the prescribed medication regimen exceeding 20%, use of medications that may interfere with the study interventions (including nonsteroidal anti-inflammatory drugs and anticonvulsants) unwillingness to continue participation in the study.

**Age**

From **18 years** old to **40 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **136**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

articipants will be randomly allocated to the study groups at the individual level, using an allocation ratio of 1:1:1:1. A block randomization method with variable block sizes will be used to generate the allocation sequence in order to maintain a relative balance in the number of participants across the four groups while reducing the predictability of subsequent allocations. The randomization sequence will be generated using statistical software or a validated computer-based random number generation tool. After obtaining informed consent, each eligible participant will be assigned to one of the four groups according to the predetermined randomization sequence: the control group, the oral Anahil group, the topical 1% phenytoin cream group, or the combined treatment group. Stratified randomization will not be used. To ensure allocation concealment, the randomization sequence will be held by an individual independent of the participant recruitment and outcome assessment processes. The allocation of each participant will remain concealed from the researcher responsible for recruitment and the outcome assessor until the participant has been enrolled in the study and their eligibility has been confirmed. Outcome assessments will be performed by an assessor who is blinded to group allocation.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, participants and outcome assessors will be blinded to group allocation. To maintain participant blinding, an oral placebo and a topical placebo corresponding to the study interventions will be used. These placebos will be made as similar as possible to the active products in terms of appearance, color, odor, and packaging. Outcome assessments, including episiotomy wound healing using the REEDA scale and pain intensity using the VAS scale, will be performed by a trained midwife or obstetrician who is independent of the group allocation process. The outcome assessor will not have access to information regarding participants' allocation to the study groups. Access to the group allocation list will be restricted to authorized personnel who require this information for study implementation. The blinding status of the principal investigator and other research team members will be determined according to their respective responsibilities in participant allocation, patient care, data collection, and data analysis. Where feasible, data analysis will also be performed using coded group labels, without the analyst being aware of the interventions represented by each code. The group codes will be revealed after the primary analysis has been finalized. Before enrollment, participants will be informed about the nature of the study, the potential interventions, the randomization procedure, and their rights, and written informed consent will be obtained.

**Placebo**

Used

**Assignment**

Factorial

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Hamedan University of Medical Sciences

**Street address**
Fatemyieh Hospital, Pasdaran Street, Hamadan.
**City**
hamedan
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**Postal code**
6517789971
**Approval date**
2026-09-26, 1405/07/04
**Ethics committee reference number**
IR.UMSHA.REC.1405.509

## Health conditions studied

### 1

**Description of health condition studied**
Episiotomy Wound
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
1. Episiotomy site pain intensity, measured using the Visual Analog Scale (VAS) score on the specified postpartum assessment days. 2. Episiotomy wound healing, measured using the REEDA scale score, which includes redness, edema, ecchymosis, discharge, and approximation of wound edges, on the specified postpartum assessment days.
**Timepoint**
Episiotomy site pain intensity will be measured using the Visual Analog Scale (VAS) on days 1, 3, 7, and 14 postpartum, and episiotomy wound healing will be assessed using the REEDA scale on days 3, 7, and 14 postpartum.
**Method of measurement**
Pain intensity at the episiotomy site will be measured using the Visual Analogue Scale, and episiotomy wound healing will be assessed using the Redness, Edema, Ecchymosis, Discharge, and Approximation scale.

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Control group: Participants will receive standard post-episiotomy care. For 14 days, a placebo capsule will be taken every 12 hours, and a placebo cream will be applied twice daily.
**Category**
Treatment - Drugs

### 2

**Description**
Intervention Group 1: Oral Anahil 500 mg every 12 hours, combined with placebo cream, for 14 days.
**Category**
Treatment - Drugs

### 3

**Description**
Intervention Group 2: Topical phenytoin 1% cream applied twice daily, combined with placebo capsules, for 14 days.
**Category**
Treatment - Drugs

### 4

**Description**
Intervention Group 3: Oral Anahil 500 mg every 12 hours, combined with topical phenytoin 1% cream applied twice daily, for 14 days
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
fatemiyeh hospital
**Full name of responsible person**
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## Sponsors / Funding sources

### 1

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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**
Hamedan 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**
Hamedan University of Medical Sciences
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**Position**
Assistant Professor
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## Person responsible for updating data

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

**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