Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the Use of Topical Calcipotriol Cream on Pain and Wound Healing Following Episiotomy in Primiparous Women: A Randomized Triple-Blind Clinical Trial Study

Protocol summary

Study aim

Evaluation of the Effectiveness of Topical Calcipotriol Cream on Pain and Wound Healing Following Episiotomy in Primiparous Mothers.

Design

This study is a randomized, triple-blind, parallel-design clinical trial aimed at evaluating the effect of calcipotriol cream on perineal pain intensity, episiotomy wound healing, and satisfaction among primiparous women. The study will be conducted in the obstetrics and gynecology departments of teaching hospitals in Ahvaz. The study population includes primiparous women who undergo vaginal delivery with mediolateral episiotomy. After obtaining written informed consent and assessing eligibility criteria, participants will be randomly assigned to either the intervention group (calcipotriol cream) or the control group (placebo). Wound healing, pain intensity, and patient satisfaction will be evaluated during the follow-up period. Considering a potential 20% dropout rate, the sample size was determined to be 36 participants per group, for a total of 108 participants.

Settings and conduct

A randomized, triple-blind clinical trial will be conducted on primiparous women with mediolateral episiotomy to compare the effects of calcipotriol cream, placebo, and standard care. Wound healing, pain intensity, and patient satisfaction will be assessed. All participants and study personnel will be blinded to group allocation.

Participants/Inclusion and exclusion criteria

Primiparous women who have undergone episiotomy. Vaginal delivery with mediolateral episiotomy. Provided written informed consent to participate in the study.

Intervention groups

All primiparous women who undergo episiotomy.

Main outcome variables

Perineal pain intensity, episiotomy wound healing process, and the level of satisfaction of women regarding wound improvement and pain reduction following episiotomy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251108067909N1**
Registration date: **2025-11-18, 1404/08/27**
Registration timing: **prospective**

Last update: **2025-11-18, 1404/08/27**
Update count: **0**

Registration date

2025-11-18, 1404/08/27

Registrant information

Name

ghazal mohammadzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3235 6910

Email address

ghazalmzade2020@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-21, 1404/08/30

Expected recruitment end date

2026-03-15, 1404/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Use of Topical Calcipotriol Cream on Pain and Wound Healing Following Episiotomy in Primiparous Women: A Randomized Triple-Blind Clinical Trial Study

Public title

Evaluation of the Use of Topical Calcipotriol Cream on Pain and Wound Healing Following Episiotomy in Primiparous Women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

primiparous women who have undergone an episiotomy Vaginal delivery with a mediolateral episiotomy Having provided written informed consent to participate in the study

Exclusion criteria:

Participants with underlying medical conditions such as diabetes, dermatologic diseases, immunodeficiency, or autoimmune disorders were excluded from the study. Women who reported taking supplements or medications containing vitamin D or similar topical creams in the past two weeks. The use of topical or oral medications with potential effects on wound healing. Participants with a known allergy to creams or ointments containing vitamin D. Unwillingness to participate in the study.

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, permutation blocks are used for the characteristics of individuals. First, 9 combinations of three treatments are written as BBAACCABC, CCBBAAABC, CBACBACBA, BACBACBAC, for example. Then, as an example, one of the highly specific combinations can be given to each block to provide the necessary sample, which the individuals selected in this study are collected as.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, participants, clinical caregivers, the principal investigator, the outcome assessor, and the data analyst will be blinded to group allocation. The calcipotriol cream and the placebo cream will be identical in color, odor, consistency, and packaging, and will be labeled with numerical codes (e.g., A and B) by an independent individual who will not be involved in the implementation of the study. Only this individual will have knowledge of the actual content corresponding to each code. Participants in the simple control group will not receive any cream; however, their data will be included in the final analysis using anonymous codes, ensuring that the data analyst remains unaware of group assignments. Thus, participants and their caregivers will be blinded to the type of cream (drug or placebo), the data collector will not be informed of group allocation, and data analysis will be performed in a blinded manner based on confidential coding.

Placebo

Used

Assignment

Parallel

Other design features

This study is a randomized, controlled clinical trial with three parallel groups. Participants will be randomly assigned to one of the following three groups: the intervention group, which will receive calcipotriol cream applied to the episiotomy site; the placebo control group, which will receive a placebo cream identical in appearance, color, odor, and packaging to the calcipotriol cream but without the active ingredient; and the no-treatment control group, which will not receive any cream on the episiotomy site.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Ahvaz Jondishapur University of Medical Sciences

Street address

Golestan Boulevard, Shahrivar Street

City

Ahvaz

Province

Khouzestan

Postal code

6136844845

Approval date

2025-11-04, 1404/08/13

Ethics committee reference number

IR.AJUMS.REC.1404.411

Health conditions studied

1

Description of health condition studied
Episiotomy.
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Episiotomy wound healing based on REEDA criteria
Timepoint
Days 3-5-10
Method of measurement
Based on the characteristics of redness, inflammation, wound distance, and discharge

2

Description
Episiotomy pain based on visual pain diagnosis
Timepoint
Day 3,5,10
Method of measurement
Based on visual analogue scale

3

Description
Women's satisfaction with wound healing and pain reduction
Timepoint
days 3-5-10
Method of measurement
Based on the researcher-made satisfaction form

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Women who are experiencing their first childbirth and are scheduled to receive topical calcipotriol cream.
Category
Rehabilitation

2

Description
Control group: Women who are experiencing their first childbirth and will not receive calcipotriol cream.
Category
Rehabilitation

3

Description
Intervention group: Women who are experiencing their first childbirth and are receiving placebo cream.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Ali Wefaq Nematollahi
Street address
Pase 2, Padadshahr, Hejrat Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Mohammad Hossein Sarmast Shushtari
Street address
Golestan Highway-Jundishapour University, Ahvaz
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6135715794
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Ahvaz.Elearning@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Ghazal
Position
Master's student
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Bachelor
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All available data from research subjects will be shareable after being de-identified through coding.
When the data will become available and for how long
Access to data and documentation will begin at the same time as the results are published.
To whom data/document is available
The data will only be accessible to researchers working in scientific and academic institutions after identifying their identity and the purpose of accessing the data.
Under which criteria data/document could be used
The data will be used to substantiate and more accurately examine the study, as well as to use it for larger studies.
From where data/document is obtainable
To receive data, please contact the corresponding author of the study at Parvinabedi@ymail.com.
What processes are involved for a request to access

data/document

To request, send your email to the responsible executive and your request will be responded to within 2-5 business days.

Comments