Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Topical Application of a Cream Containing Hydroalcoholic Extract of Rhus coriaria (Red Sumac) Seeds on the Severity of Episiotomy Pain and Wound Healing in Women Following Vaginal Delivery

Protocol summary

Study aim

To determine the effect of topical application of a cream containing hydroalcoholic extract of red sumac fruit seed on the severity of episiotomy pain and wound healing in women undergoing vaginal delivery

Design

This is a randomized, controlled clinical trial with parallel groups and a triple-blind design, which will be conducted on 80 women undergoing vaginal delivery with episiotomy. Participants will be randomly allocated to the intervention and control groups using the block randomization method.

Settings and conduct

Bahlool Hospital in Gonabad and Vali-e-Asr in Birjand

Participants/Inclusion and exclusion criteria

Women aged 18–45 years with term singleton pregnancies who underwent uncomplicated vaginal delivery with a second-degree mediolateral episiotomy, were in good general health, provided informed consent to participate in the study, and had no diseases, pregnancy-related complications, or use of medications affecting wound healing were included in the study

Intervention groups

In the intervention group, mothers will receive red sumac seed extract cream along with routine postpartum care. After episiotomy repair, they will be instructed to apply the cream twice daily to the wound site. Wound healing and pain will be assessed using the REEDA and Visual Analog Scales on postpartum days 1, 5, and 10. Mothers will also receive education on perineal care, daily records, and follow-up.In the control group, mothers will receive the same postpartum care and educational instructions provided to the intervention group; however, instead of the cream containing hydroalcoholic extract of red sumac seed, they will use a placebo cream.

Main outcome variables

Episiotomy pain intensity and episiotomy wound healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260803070513N1**
Registration date: **2026-08-08, 1405/05/17**
Registration timing: **prospective**

Last update: **2026-08-08, 1405/05/17**
Update count: **0**

Registration date

2026-08-08, 1405/05/17

Registrant information

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-06, 1405/06/15

Expected recruitment end date

2026-12-06, 1405/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Topical Application of a Cream Containing Hydroalcoholic Extract of Rhus coriaria (Red Sumac) Seeds on the Severity of Episiotomy Pain and Wound Healing in Women Following Vaginal Delivery

Public title

Effect of Topical Application of a Cream Containing Hydroalcoholic Extract of Rhus coriaria (Red Sumac) Seeds on the Severity of Episiotomy Pain and Wound Healing in Women Following Vaginal Delivery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Vaginal delivery without the use of instrumental assistance Term pregnancy (38–42 weeks of gestation) Singleton pregnancy with cephalic presentation in mothers with good physical and mental health, based on medical records and maternal history Absence of precipitous or prolonged labor Normal pre-pregnancy body mass index (BMI: 19.8–26 kg/m²) at the beginning of pregnancy (before 12 weeks of gestation), based on medical records and maternal history Willingness to participate in the study and provision of written informed consent Primiparous and secundiparous women (first or second vaginal birth) Maternal age between 18 and 45 years Ability to read and write and communicate effectively with the researcher Routine use of standard prenatal supplements during pregnancy Rupture of membranes lasting no longer than 10 hours before delivery Episiotomy without extension or associated perineal tear No history of substance abuse or use of medications known to interfere with wound healing (e.g., anticoagulants, antidepressants, antiepileptic drugs, or immunosuppressive agents), and no history of hypersensitivity to topical medications, based on maternal self-report Complete spontaneous placental delivery A live, apparently healthy newborn with a normal birth weight (2,500–4,000 g) who roomed-in with the mother No maternal anemia, based on medical records and maternal history Uncomplicated vaginal delivery without any intrapartum complications, as documented in the partograph Mediolateral second-degree episiotomy performed during spontaneous vaginal delivery without complications (e.g., hematoma or the need for interventions beyond routine repair), with repair performed according to the national clinical guideline A healthy, term singleton infant with normal birth weight who did not require hospitalization during the first 10 days of life No history of dermatological disease, systemic disease, psychiatric disorders, genital infections, or pregnancy-related complications, based on medical records and maternal history No use of corticosteroids, immunosuppressive agents, or enoxaparin during pregnancy, based on medical records and maternal history

Exclusion criteria:

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

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

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants were recruited using a continuous (consecutive) sampling method. Women who underwent vaginal delivery with episiotomy and met the study eligibility criteria were enrolled consecutively as they became available. Eligible participants were then randomly assigned to either the intervention or placebo group using block randomization with variable block sizes of four. Initially, the six possible allocation sequences for blocks of four (BBAA, BABA, ABBA, BAAB, AABB, and ABAB) were generated, and each sequence was assigned a number from 1 to 6. Subsequently, a random number between 1 and 6 was selected, and participants were allocated according to the corresponding block sequence, with B representing the intervention group and A representing the placebo group. This process was repeated until the required sample size was achieved.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study was designed as a triple-blind clinical trial. The participants, the researcher administering the intervention, the outcome assessor, and the statistician responsible for data analysis will all be blinded to the treatment allocation. The creams containing hydroalcoholic extract of red sumac (Rhus coriaria) seed and the placebo will be identical in color, odor, consistency, texture, and packaging and will be identified only by a unique code. The collected data will be entered into the statistical software using coded identifiers, and the allocation codes will remain confidential until the completion of the statistical analysis.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Gonabad University of Medical Sciences

Street address

No. 25, Baharestan Street, Farmandari Town, Qaen City, Qaenat County, South Khorasan Province, Iran

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Approval date

2026-02-16, 1404/11/27

Ethics committee reference number

IR.GMU.REC.1404.160

Health conditions studied

1

Description of health condition studied

Pain intensity and episiotomy wound healing

ICD-10 code

O90.1

ICD-10 code description

O70

Primary outcomes

1

Description

Severity of episiotomy pain Episiotomy wound healing

Timepoint

Postpartum Day 1, Before Discharge, Postpartum Day 5, and Postpartum Day 10

Method of measurement

Pain intensity will be assessed using the Visual Analog Scale (VAS), and wound healing will be evaluated using the REEDA Wound Healing Scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Following episiotomy repair and transfer of the mother to the postpartum ward, in addition to routine postpartum care, the mother will receive a cream containing hydroalcoholic extract of red sumac seeds. The mother will be instructed to apply a 1–2 cm layer of the cream (depending on the wound size) to the skin of the episiotomy area using a clean finger twice daily, ensuring that the entire length of the skin wound is covered. The application of the cream will continue until the tenth postpartum day. Pain intensity and perineal wound status will be assessed on the first postpartum day, before discharge, the fifth postpartum day, and the tenth postpartum day.

Category

Treatment - Drugs

2

Description

Control group: Following episiotomy repair and transfer of the mother to the postpartum ward, in addition to routine postpartum care, the mother will receive a placebo cream that is similar to the cream containing hydroalcoholic extract of red sumac seeds in terms of appearance, color, odor, consistency, packaging, and method of application, but does not contain the hydroalcoholic extract of red sumac seeds. The mother will be instructed to apply a 1–2 cm layer of the cream (depending on the wound size) to the skin of the episiotomy area using a clean finger twice daily, ensuring that the entire length of the skin wound is covered. The application of the placebo cream will continue until the tenth postpartum day. Pain intensity and perineal wound status will be assessed on the first postpartum day, before discharge, the fifth postpartum day, and the tenth postpartum day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

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Full name of responsible person

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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
Gonabad 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

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Contact
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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