Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of Pomegranate (Punica granatum) peel extract ointment on pain severity and episiotomy wound healing: a randomized clinical trial

Protocol summary

Study aim
Determining the Effect of Pomegranate Peel Extract Ointment on Pain Intensity and Episiotomy Wound Healing

Design
A three-arm, controlled, parallel-group, randomized, phase 3 clinical trial involving 120 patients. Random allocation software will be used for randomization

Settings and conduct
This research is a triple-blind, randomized clinical trial that will be conducted at Mo'tazedi Hospital in Kermanshah, in the postpartum and gynecology outpatient departments. The ointments of pomegranate peel extract and placebo will be prepared with similar packaging and different codes, which the pharmacist will be aware of. The distribution of the intervention will be based on pre-determined codes assigned to participants by a trained colleague. The researcher will only record the participant's code when assessing the outcomes and will not be aware of the intervention type (medication, placebo, or cleansing serum) assigned to the participant. The statistical analyst will also be blinded, and the disclosure of codes will occur after the completion of the statistical analysis. The ointments will be used twice a day for 10 days, and the cleansing serum will be used three times a day for 10 day

Participants/Inclusion and exclusion criteria
Entering Criteria: Postpartum women؛ Age between 18 and 35 years؛ Iranian nationality؛ Gestational age between 37 and 42 weeks؛ Presence of a single fetus with a cephalic presentation. Not Entering Criteria: Rupture of the amniotic sac for more than 24 hours؛ Presence of a condition that impairs wound healing؛ Severe anemia, History of hypersensitivity to topical or herbal medications

Intervention groups
Intervention Group 1: Received pomegranate skin ointment Intervention Group 2: Received a placebo ointment Control Group: Received routine care

Main outcome variables
Pain severity of episiotomy؛ Wound healing of episiotomy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260423069137N1**
Registration date: **2026-05-09, 1405/02/19**
Registration timing: **prospective**

Last update: **2026-05-09, 1405/02/19**
Update count: **0**

Registration date
2026-05-09, 1405/02/19

Registrant information

Name
Sahar Nazarabadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-05-21, 1405/02/31

Expected recruitment end date
2026-08-22, 1405/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Pomegranate (Punica granatum) peel extract ointment on pain severity and episiotomy wound healing: a randomized clinical trial

Public title

Evaluation of the effect of Pomegranate peel ointment in episiotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age between 37 and 42 completed weeks Maternal age between 18 and 35 years Body mass index (BMI) within the range of 18.6 to 30 Iranian nationality Resident of Kermanshah Province Ability to read and write Singleton pregnancy with cephalic presentation Neonatal birth weight between 2,500 and 4,000 grams Vaginal delivery with mediolateral episiotomy, without perineal tear and without the use of assisted delivery tools (forceps or vacuum)

Exclusion criteria:

Prolonged rupture of membranes lasting more than 24 hours Severe anemia during pregnancy (hemoglobin level below 7) Consumer of cigarettes, alcohol, and drugs Presence of any underlying condition that impairs wound healing (including chronic systemic diseases, cardiopulmonary disorders, connective tissue diseases, anemia, diabetes, malnutrition, hemophilia, psychiatric disorders, and renal failure), as well as obstetric complications such as gestational diabetes, preeclampsia, eclampsia, coagulation disorders, placental abruption, chorioamnionitis, and immune system deficiencies, based on the individual’s statement and medical/midwifery records Use of any medications that may affect wound healing, such as corticosteroids, anticoagulants, antiepileptic drugs, immunosuppressants, broad-spectrum antibiotics, and chemotherapeutic agents Labor dystocia and prolongation of the stages of labor History of hypersensitivity to topical or herbal medications, as reported by the individual

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be divided into three groups by random allocation using the Random Allocation software: the group receiving pomegranate peel extract ointment, the group receiving placebo ointment, and the routine care group including washing the wound site with normal saline. Allocation of participants to the groups will be done using random numbers to prevent selection bias.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study will be conducted using a three-blind design. For intervention allocation, pre-determined codes prepared by the pharmacist will be used. Accordingly, drug or placebo ointment and normal saline solution will be assigned in a coded manner by a trained colleague, according to these codes, to the participants. During outcome assessment, the investigator will be unaware of the type of intervention assigned (drug, placebo, or saline wash) and will only record the participant’s code. The statistician will also remain blinded, and code unblinding will be performed only after completion of the statistical analysis

Placebo

Used

Assignment

Parallel

Other design features

This is a three-group study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee/Working Group in Research of the Faculties of Pharmacy, Nursing, and Midwifery — Sh

Street address

Faculty of Nursing & Midwifery, Vali-e Asr Street, at the intersection of Neayesh Avenue, opposite Shahid Rajaee Heart Hospital, Tehran

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2026-05-03, 1405/02/13

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1405.052

Health conditions studied

1

Description of health condition studied
Episiotomy
ICD-10 code
O70
ICD-10 code description
Perineal laceration during delivery

Primary outcomes

1

Description
Pain intensity score on the Visual Analog Scale for pain.
Timepoint
Before intervention (2 hours postpartum) and on the first, fifth, and tenth days postpartum
Method of measurement
Visual Analog Scale

2

Description
Wound healing score on the Redness, Edema, Echymosis, Discharge, Approximation scale
Timepoint
Before intervention (2 hours postpartum) and on the first, fifth, and tenth days postpartum
Method of measurement
Redness, Edema, Echymosis, Discharge, Approximation scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Recipients of pomegranate peel extract ointment. In this study, pomegranate peel was obtained from the herbal market (herbalist shop), and after identity confirmation, it was dried in the shade and powdered using a grinder. Subsequently, the extract was obtained by soaking in methanol. The pure extract was then mixed with Eucerin at a 2% concentration and filled into 60-gram tubes. The filled ointments were autoclaved and finally, applied to the wounds by the study participants, twice a day (every 12 hours) for 10 days. At the beginning of the intervention, all participants in all three groups received uniform training on how to cleanse the perineum with normal saline, 3 times a day for 10 days, dry the area, and maintain general perineal hygiene. In this intervention group, prior to use, a sensitivity test was performed under the supervision of the researcher. A small amount of the ointment was applied to the inner surface of the arm, and if no reaction occurred within 30 minutes, the use of the ointment would commence from the first day after childbirth.Participants in this group, after washing their hands and cleansing and drying the perineum, would apply 2 grams of the ointment evenly to the wound site and use a clean sanitary pad after 1–2 minutes. Ointment application continued twice daily with a 12-hour interval for 10 days. Participants would be instructed to visit the gynecology clinic of Motazeddi Hospital in Kermanshah on the fifth and tenth days after childbirth for evaluation.To follow up with participants, their phone numbers were obtained at the beginning of the study and their accuracy verified through phone calls. Daily reminder text messages were also planned. If participants did not show up at the scheduled times, phone follow-up would be conducted, and evaluations would be performed at their homes with their coordination and consent. Participants would be trained to contact the researcher in case of any problems or complications such as sensitivity, pain, itching, burning, fever, and chills, so that necessary actions could be taken.
Category
Treatment - Drugs

2

Description
Intervention group 2: Recipients of placebo ointment. This ointment contains the base materials of the drug (Eucerin), which is completely similar to the main drug in terms of appearance, color, and consistency, filled into 60-gram tubes, and autoclaved. Finally, it is applied to the wounds by the study participants, twice a day (every 12 hours) for 10 days. At the beginning of the intervention, all participants in all three groups received uniform training on how to cleanse the perineum with normal saline, 3 times a day for 10 days, dry the area, and maintain general perineal hygiene. In this intervention group, prior to use, a sensitivity test was performed under the supervision of the researcher. A small amount of the ointment was applied to the inner surface of the arm, and if no reaction occurred within 30 minutes, the use of the ointment would commence from the first day after childbirth.Participants in this group, after washing their hands and cleansing and drying the perineum, would apply 2 grams of the ointment evenly to the wound site and use a clean sanitary pad after 1–2 minutes. Ointment application continued twice daily with a 12-hour interval for 10 days. Participants would be instructed to visit the gynecology clinic of Motazeddi Hospital in Kermanshah on the fifth and tenth days after childbirth for evaluation.To follow up with participants, their phone numbers were obtained at the beginning of the study and their accuracy verified through phone calls. Daily reminder text messages were also planned. If participants did not show up at the scheduled times, phone follow-up would be conducted, and evaluations would be performed at their homes with their coordination and consent. Participants would be trained to contact the researcher in case of any problems or complications such as sensitivity, pain, itching, burning, fever, and chills, so that necessary actions could be taken.
Category
Placebo

3

Description
Control group: Routine care group (Saline solution). In participants of this group, the episiotomy incision site is cleansed with 1000 ml of 0.9% sodium chloride physiological saline solution (product of Iran Injectable and Derivative Company) three times a day for 10 days. After drying, clean sanitary pads are used. The researcher will provide instructions to the participants regarding drying the area and general perineal hygiene. Participants will be informed to visit the gynecology clinic of Motazeddi Hospital in Kermanshah on the fifth and tenth days postpartum for evaluation. To follow up with participants, their phone numbers will be obtained at the beginning of the study, and their accuracy will be verified through telephone calls. Additionally, daily reminder text messages will be sent. If participants do not attend appointments at the scheduled times, telephone follow-up will be conducted, and evaluations will be performed at their homes with their coordination and consent.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Motazedi Hospital

Full name of responsible person
Navid Bahremand Moghadam

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Sahar Nazarabadi

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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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
In case of a logical justification, it will be provided to the journal for publication of the article.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Demographic characteristics and findings related to the primary outcome variable will be reported in the published article

When the data will become available and for how long
After publish of article

To whom data/document is available
students and researchers at university and scientific institutions

Under which criteria data/document could be used
Other statistical analyses

From where data/document is obtainable
Dr Fatemeh Nahidi f.nahidi87@gmail.com

What processes are involved for a request to access data/document
After the request has been reviewed by the researcher (Sahr Nazarabadi), the documents may be delivered to the applicant within approximately one month.

Comments
After consultation with the research team, the data will be provided to the applicant, which will likely be a one-month process