Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of combining alum ointment and positive psychology on episiotomy healing and pain intensity in primiparous women

Protocol summary

Study aim
Determining the effect of alum ointment and positive psychology on the healing and pain intensity of episiotomy in primiparous women

Design
A phase 3 clinical trial without a control group, using factorial groups, was conducted on 120 patients. Randomization was performed using an online system.

Settings and conduct
The procedure involves visiting selected teaching hospitals in the city of Rasht—upon presentation of a written letter of introduction—to collect samples. Al-Zahra Teaching Hospital, a public facility serving as a referral center for patients from other counties in the province, will be included. Subsequently, all samples will be enrolled in the study using a randomized block design (block size of 12).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Primiparous, literate women with gestational age of 38–42 weeks, BMI between 18.5–24.9, infant weight 2500–4000 g, vaginal delivery with mediolateral episiotomy without instruments, no prolonged membrane rupture, chronic constipation, or psychiatric disorders. Exclusion criteria: Unwillingness to participate, substance abuse or psychoactive drug use, incorrect ointment use, sensitivity to alum ointment, use of wound-healing drugs, episiotomy manipulation, sexual activity within 10 days postpartum, missing follow-ups, perineal injury history, chronic diseases, hospitalized or abnormal infant, or absence from more than two counseling sessions.

Intervention groups
In this study, the intervention will involve a combination of 2% alum ointment and positive psychology therapy.

Main outcome variables
Primary outcome: Pain measured by REEDA and Visual Analogue Scale (VAS) at 4, 8, 12 hours, and days 5 and 10 post-intervention. Secondary outcomes: Wound healing and adverse effects assessed by a researcher-made questionnaire at the same intervals.

General information

Reason for update
Due to a change in the study location, information regarding the randomization method and other details related to the research site has been updated.

Acronym

IRCT registration information
IRCT registration number: **IRCT20250915067251N1**
Registration date: **2025-09-25, 1404/07/03**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-02, 1405/07/10**
Update count: **1**

Registration date
2025-09-25, 1404/07/03

Registrant information

Name
Hasti Shenasandeh

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
2025-09-23, 1404/07/01

Expected recruitment end date
2026-03-20, 1404/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of combining alum ointment and positive psychology on episiotomy healing and pain intensity in primiparous women

Public title
The effect of combining alum ointment and positive psychology on episiotomy healing and pain intensity in primiparous women
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Ability to read and write Being a primiparous woman Gestational age between 38 and 42 completed Body mass index (BMI) in the range of 18.5 to 24.9 Newborn weight between 2500 and 4000 grams Vaginal delivery with mediolateral No rupture of membranes for more than 18 hours No simultaneous psychiatric or psychological interventions No chronic constipation Absence of any significant psychiatric disorders,anxiety ,depression or neuropsychological symptoms
Exclusion criteria:
Addiction to drugs or use of psychoactive substances Allergy to alum ointment Use of medications that affect wound healing during the study Re-manipulation of the episiotomy site after initail repair Engaging in sexual intercourse within the first 10 days postpartum failure to return to the hospital one days 5 and 10 for episiotomy healing assessment History of trauma or previous surgery,and presence of visible perineal Having diseases that interfere with wound healing, such as chronic illnesses ,heart, kidney or lung disease ,connective tissue disorders, diabetes, anemia, hemophilia or malnutrition Neonatal hospitalization or presence of congenital abnormalities in the newborn Missing more than two counseling sessions
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, four groups of primiparous women will be assigned to three intervention groups and one control group. A total of 120 primiparous women undergoing vaginal delivery with episiotomy will be recruited from selected teaching hospitals in Rasht. Random assignment will be conducted using blocks of 12 with a 1:1:1:1 allocation ratio. Randomization will be performed via the online system at https://www.sealedenvelope.com/simple-randomiser/v1/lists. A total of ten blocks of 12 will be used to generate the 120 randomized assignments. Eligible participants will be assigned to the respective groups sequentially according to the list. The intervention assignments will be numbered and placed in sealed envelopes. Given the nature of the interventions in this study (counseling, herbal ointment, and placebo), complete blinding across all groups is not feasible. However, the following measures have been implemented to minimize the risk of bias: Blinding of participants in the ointment groups: The two types of ointment (herbal and placebo) have been designed to be identical in appearance, color, odor, packaging, and method of application, ensuring that neither the participants nor the researchers responsible for outcome assessment are aware of the specific ointment type (herbal or placebo) being used. Thus, double-blinding is maintained for this part of the study. Counseling group: Due to the fundamental difference between this intervention (counseling) and those of the other groups, blinding is not possible for this group. However, the statistical analyst and the assessors of the final results will remain unaware of the participants' group assignments (analyst blinding). Overall, the study is designed as a single-blind trial, with blinding of participants across the treatment groups and the final data analyst to minimize potential bias in the interpretation of results. For each block of eight individuals, the randomization sequence for group assignments (A, B, C, D) was placed together in a numbered, sealed envelope; each envelope contained the assignments for eight participants. As each participant enrolled, the envelope corresponding to their sequence number was opened to determine their assigned group.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kerman University of Medical Sciences
Street address
Unit 3, No. 9,Azadkhoo Alley, Sq 40, Narmak
City
Tehran
Province

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Postal code

۱۶۴۷۶۱۷۱۸۱

Approval date

2025-09-15, 1404/06/24

Ethics committee reference number

IR.KMU.REC.1404.311

Health conditions studied

1

Description of health condition studied

The effect of combining alum ointment and positive psychology on episiotomy healing and pain intensity in primiparous women

ICD-10 code

O70

ICD-10 code description

Perineal laceration during delivery

Primary outcomes

1

Description

The primary outcome of the present study is pain.

Timepoint

It is measured at intervals of 4, 8, and 12 hours, and on days 5 and 10 after the intervention.

Method of measurement

Through the REDA scale and the visual pain scale.

Secondary outcomes

1

Description

Healing of the episiotomy wound is considered a secondary outcome

Timepoint

It is completed at intervals of 4, 8, and 12 hours, and on days 5 and 10 after the intervention.

Method of measurement

Adverse effects are assessed using a self-designed questionnaire.

Intervention groups

1

Description

Intervention group:The intervention consists of applying alum ointment twice daily for 10 days as topical treatment.

Category

Treatment - Drugs

2

Description

Intervention group:Participants will receive alum ointment along with positive psychology counseling. First, they will attend one individual face-to-face psychotherapy session lasting 30 to 45 minutes at the hospital. Then, they will be treated with the topical ointment twice daily for 10 days, while simultaneously receiving 10 sessions of 45-minute positive psychology counseling via virtual meetings.

Category

Treatment - Other

3

Description

Intervention group: Positive psychology counseling begins with an initial individual face-to-face session lasting 30 to 45 minutes at the hospital.

Category

Treatment - Other

4

Description

Control group: Placebo ointment: Participants will be treated with the topical ointment twice daily for 10 days. This ointment is similar in shape and appearance to the alum ointment.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasht Alzahra Hospital

Full name of responsible person

Hasti Shenasandeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

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
Kerman 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
Kerman University of Medical Sciences

Full name of responsible person
Hasti Shenasandeh

Position
Masters student in Counseling in Midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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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