Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

“Effect of Jujube Fruit Lotion on Pain intensity and Episiotomy Wound Healing in Postpartum Women at Allameh Behlol Gonabadi and Hazrat Abolfazl Hospitals, Gonabad and Kashmar, 2025–2026: A Triple-Blind Randomized Clinical Trial”

Protocol summary

Study aim
Effect of jujuba Lotion on Episiotomy Pain and Healing

Design
Participants were randomized 1:1 via permuted blocks of four by an independent statistician. Allocation was concealed using sequentially numbered, opaque sealed envelopes. Sample size was estimated in G*Power 3.1.9.2 using an independent t-test (α=0.05, power=0.80); with 25% attrition, 42 participants per group were planned

Settings and conduct
After ethical approval and IRCT registration, the study was conducted at Allameh Bohlol and Hazrat Abolfazl hospitals. Participants were recruited by convenience sampling, gave informed consent, completed questionnaires privately, received standard perineal care, and underwent a skin patch test (0.1 mL lotion on the inner forearm). Absence of erythema, pruritus, or burning after 2 h was required to proceed

Participants/Inclusion and exclusion criteria
Inclusion: Females 18–45; primiparous/multiparous; 37–42 weeks gestation; singleton (neonate 2500–4000g); BMI 18.5–29.9; mediolateral episiotomy; hospitalization <24h; informed consent.Exclusion: Jujube allergy; perineal/genital infection; systemic diseases (e.g., diabetes, autoimmune, severe anemia); use of corticosteroids, immunosuppressants, anticoagulants, NSAIDs, zinc/vitamin E, or other topicals; complicated delivery (e.g., tears, hematoma, instrumental); rapid labor (<3h); psychiatric history; blood transfusion; ruptured membranes >24h; withdrawal.

Intervention groups
Prior to the intervention, all participants received standardized perineal care instructions, and a skin sensitivity patch test (on the forearm for 2 hours) was performed to ensure the safety of the jujube fruit lotion

Main outcome variables
Episiotomy wound healing and pain relif

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260603069629N1**
Registration date: **2026-06-23, 1405/04/02**
Registration timing: **prospective**

Last update: **2026-06-23, 1405/04/02**
Update count: **0**

Registration date
2026-06-23, 1405/04/02

Registrant information
Name
Sajede Akbari
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 5523 8562
Email address
akbari.s.stu@gmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-07-10, 1405/04/19
Expected recruitment end date
2026-10-11, 1405/07/19
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

"Effect of Jujube Fruit Lotion on Pain intensity and Episiotomy Wound Healing in Postpartum Women at Allameh Behlol Gonabadi and Hazrat Abolfazl Hospitals, Gonabad and Kashmar, 2025–2026: A Triple-Blind Randomized Clinical Trial"

Public title

Effect of Jujube Fruit Lotion on Pain intensity and Episiotomy Wound Healing

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women in their first or second childbirth Maternal age between 18 and 45 years Gestational age between 37 and 42 completed weeks Maternal BMI in the normal to overweight range (18.5–29.9) Undergoing mediolateral episiotomy during normal vaginal delivery Providing informed consent to participate in the study Delivering a live singleton neonate with a normal birth weight (2500–4000 g) Hospital stay of less than 24 hours

Exclusion criteria:

History of perineal skin diseases Allergy to jujube or topical herbal products Presence of active genital infection Systemic diseases affecting wound healing Use of corticosteroid medications Use of nonsteroidal anti-inflammatory drugs above routine doses Use of immunosuppressive medications Occurrence of a stressful event or major incident during the study period Use of anticoagulant medicationsHigh-dose use of supplements affecting wound healingConcurrent use of other topical products on the episiotomy site Occurrence of complications affecting perineal healing during or after childbirth Rapid,difficult, or instrumental delivery Lack of a companion or caregiver in the hospital Unwillingness to continue participation in the study History of psychiatric disorders or postpartum depression Receipt of blood or blood products during or after childbirthProlonged rupture of membranes (more than 24 hours before delivery)

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

A random allocation sequence for assigning participants to the intervention and control groups will be generated by an independent statistician (data analyst) using permuted blocks of four. Allocation codes will be placed in sequentially numbered, opaque, sealed envelopes and will be opened by the researcher only at the time of participant enrollment. Therefore, the researcher will remain unaware of the assigned group until the moment of allocation, ensuring allocation concealment.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is designed as a triple-blind randomized controlled trial. Participants, the intervention researcher, the outcome assessor, and the statistical analyst will all be blinded to the type of intervention. The lotions (containing Ziziphus jujuba fruit extract and placebo) were prepared to be identical in color, scent, consistency, and packaging, and will be coded uniquely. Data will be entered into the statistical software in a coded format, and the codes will remain confidential until the end of the analysis. The intervention group will receive standard hospital care plus the Ziziphus jujuba fruit lotion. The control group will receive standard hospital care and the base lotion (placebo). The placebo consists of a base lotion without the Ziziphus jujuba extract, which has been standardized to match the appearance of the active lotion.

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

the roadside of the Asian highway

City

Gonabad

Province

Razavi Khorasan

Postal code

9671967557

Approval date

2026-04-12, 1405/01/23

Ethics committee reference number

IR.GMU.REC.1405.028

Health conditions studied

1

Description of health condition studied
Pain intensity and Episiotomy Wound Healing
ICD-10 code
O90.1
ICD-10 code description
Disruption of perineal obstetric wound

2

Description of health condition studied
Pain intensity and Episiotomy Wound Healing
ICD-10 code
O70
ICD-10 code description
Perineal laceration during delivery

Primary outcomes

1

Description
Episiotomy Wound Healing
Timepoint
On postpartum days 1, 5, and 10
Method of measurement
REEDA criteria: R = Redness E = Edema E = Ecchymosis D = Discharge A = Approximation

2

Description
Pain intensity
Timepoint
On postpartum days 1, 5, and 10
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Pain reduction
Timepoint
On postpartum days 1, 5, and 10
Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group:Participants allocated to the intervention group will receive routine postpartum care in addition to a topical lotion containing 1% hydroalcoholic extract of jujube fruit (Ziziphus jujuba Mill.). The extract, with 100% purity, will be obtained from the Giah Kala Herbal Refinery. The lotion will be formulated using a standard lotion base and packaged in 25-mL dark-colored bottles.Participants will be instructed to apply approximately 0.5 mL of the 1% jujube lotion as a thin layer over the episiotomy wound twice daily (morning and evening) for 10 consecutive days following childbirth, after cleansing and drying the perineal area. A skin sensitivity test will be performed before initiating the intervention to ensure the absence of allergic reactions. Standardized instructions regarding product application will be provided, and daily reminder messages will be sent to enhance adherence to the intervention protocol
Category
Treatment - Drugs

2

Description
Control group:Participants allocated to the control group will receive routine postpartum care in addition to a placebo lotion. The placebo will consist of the same lotion base used in the intervention group but without the jujube extract and will be identical in appearance, odor, consistency, packaging, and storage conditions to ensure blinding.Participants will be instructed to apply approximately 0.5 mL of the placebo lotion as a thin layer over the episiotomy wound twice daily (morning and evening) for 10 consecutive days following childbirth, after cleansing and drying the perineal area. The application procedure, duration of use, participant education, and follow-up schedule will be identical to those of the intervention group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Allameh Bohlool Gonabadi Hospital
Full name of responsible person
Sajede Akbari
Street address
Allameh Bohlool Gonabadi Hospital, Parastar Blvd, Saadi St, Gonabad, Iran
City
Gonabad
Province
Razavi Khorasan
Postal code
9691699967
Phone
+98 51 5723 6833
Email
info@gmu.ac.ir

2

Recruitment center

Name of recruitment center
Hazrat Abolfazl Hospital, Kashmar
Full name of responsible person
SajedeAkbari
Street address
Sina Sq., Moallem Town
City
Kashmar
Province
Razavi Khorasan
Postal code
۹۱۷۷۸۹۹۱۹۱
Phone
+98 51 5523 8300
Email
webda@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Dr. Ali Firoozi
Street address
Asian Roadside
City
Gonabad
Province
Razavi Khorasan
Postal code
969169996
Phone
+98 51 5722 3028
Email
info@gmu.ac.ir
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

Person responsible for general inquiries

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Akbari Sajede
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Asian Roadside
City
Gonabad
Province
Razavi Khorasan
Postal code
969169996
Phone
+98 51 5722 3028
Email
akbari.s.stu@gmu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Sajede Akbari
Position
Midwife
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Asian Highway roadside
City
Gonabad
Province
Razavi Khorasan
Postal code
9671967557
Phone
+98 51 5523 8562
Fax
Email
akbari.s.stu@gmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Gonabad University of Medical Sciences
Full name of responsible person
Akbari Sajede
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery

Street address
Asian Roadside
City
Gonabad
Province
Razavi Khorasan
Postal code
969169996
Phone
+98 51 5722 3028
Email
info@gmu.ac.ir

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
Yes - There is 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
The complete clinical trial dataset, including all variables related to pain intensity and episiotomy wound healing in both the intervention and control groups. All direct and indirect personal identifiers will be removed, and the data will be fully de-identified to protect participants' privacy. The codebook and variable guide, including definitions of all variables, measurement scales, and coding instructions to facilitate reproducibility of the analyses. The study protocol and data collection instruments, including the final approved protocol, questionnaires, and checklists used to assess wound healing and pain intensity. The statistical analysis files (syntax/scripts), including the codes used in statistical software for data cleaning, management, and analysis, allowing other researchers to reproduce the results.
When the data will become available and for how long
Access to the study data and documentation will be granted starting 6 months post-publication
To whom data/document is available
Data and documentation will be available upon request to qualified researchers and institutions
Under which criteria data/document could be used
Research Purpose: Data must be used strictly for non-commercial, ethical scientific research. Security & Privacy: Users must not attempt to re-identify participants or transfer the data to third parties. Acknowledgment: Any publication or output resulting from these data must formally cite the original study and its investigators. Compliance: The request must include a defined analysis plan and confirmation of ethical alignment with the study's original scope.
From where data/document is obtainable
The Principal Investigator is responsible for reviewing and responding to all scientific requests. Applicants are required to submit their formal request, including the research project title and a brief description of the study's objectives, to the following email address: Email: akbari.s.stu@gmu.ac.ir Subject Line: Data Request: Effect of Jujube Lotion on Episiotomy Healing 2. Secondary Contact: Clinical Research Development Office If you do not receive a response within 15 working days, you may forward your request to the Clinical Research Development Office at Gonabad University of Medical Sciences: Mailing Address: Clinical Research Development Office, Vice-Chancellery for Research and Technology, Gonabad University of Medical Sciences, Gonabad, Iran. Phone: +98 51 5722 3028
What processes are involved for a request to access data/document
Applicants are required to submit a formal written request to the Principal Investigator via email, including their full name, institutional affiliation, contact information, the specific study title, and a brief description of the intended purpose of the requested data or documentation. All requests will be reviewed by the research team to ensure alignment with the study's objectives and ethical requirements. If necessary, the applicant may be requested to provide supplementary information, such as a detailed analysis plan or proof of institutional ethical approval. Upon final approval, the specific terms of data usage will be communicated, and the documents or de-identified data files will be shared via secure channels. Regarding the timeline, the initial review process typically takes 5–7 working days. If additional clarification is required, further communication may take up to 5 working days, and the final preparation and release of the materials usually require 10–15 working days following final approval. Consequently, the entire process is estimated to be completed within 2 to 4 weeks, depending on the completeness of the initial request and the scope of the required review.
Comments