Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of apricot kernel oil cream on pain intensity and episiotomy wound healing in primiparous women

Protocol summary

Study aim
Investigating the effect of apricot kernel oil cream on pain intensity and episiotomy wound healing in primiparous women

Design
A clinical trial with two intervention and placebo groups with parallel groups, triple blind, randomized, phase 2-3 for 76 patients. Random Allocation Software will be used for randomization.

Settings and conduct
This triple-blind research will be conducted in M. Al-Binin (S) and Hashminejad hospitals in Mashhad. In the intervention group, they will use apricot kernel oil cream every 12 hours for 10 nights. The placebo group will also use the placebo in the same way. The tools will include a demographic and midwifery information questionnaire, a visual pain scale, a Rida scale form and a drug side effects form, which will be evaluated within the first 24 hours after delivery, on the fifth day and one of the days during 10 to 14 it will take place after childbirth.

Participants/Inclusion and exclusion criteria
Inclusion criteria: signed informed consent; no use of drugs effective on wound healing; no diabetes. Exclusion criteria: abnormal bleeding after delivery; not using the cream regularly; not coming for follow-up; suffering from a disease that requires the prescription of antibiotics.

Intervention groups
The intervention group consumes 30 grams of apricot kernel oil cream tubes prepared with code A or B, topically and every 12 hours, 2 cm of the product in the first 10 days after delivery. in the control group. The placebo is a standard cold cream without apricot kernel oil and as a simple cream base, which is similar to the drug in terms of shape and can only be distinguished by the code, and the method of administration will be the same as the drug group.

Main outcome variables
Intensity of episiotomy pain; healing of episiotomy wound

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230501058041N1**
Registration date: **2023-06-20, 1402/03/30**
Registration timing: **prospective**

Last update: **2023-06-20, 1402/03/30**
Update count: **0**

Registration date
2023-06-20, 1402/03/30

Registrant information
Name
Narjes Kharazmi
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-07-01, 1402/04/10
Expected recruitment end date
2023-10-22, 1402/07/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Investigating the effect of apricot kernel oil cream on pain intensity and episiotomy wound healing in primiparous women

Public title

Investigating the effect of apricot kernel oil cream on pain and healing of episiotomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The participant has informed consent. Age between 18 and 35 years old. Must be literate and a resident of Mashhad. The gestational age should be 37 to 42 weeks. Do not have a history of sensitivity or allergy to topical medications in the past Do not use drugs effective on wound healing (glucocorticoids, anticoagulants, immunosuppressants, broad-spectrum antibiotics, and chemotherapy). Do not be addicted to drugs. Not diabetic Rupture of water bag not more than 18 hours Singleton pregnancy No history of surgery or visible lesions in the perineum. Body mass index should be between 19.8 and 30

Exclusion criteria:

The baby's weight should be more than 4000 grams. Have abnormal bleeding after delivery. Has not used the cream regularly. Allergies and infections Happening a new trauma. Do not refer for follow up. Patients with a disease need to be prescribed antibiotics. Does not want to continue participating in the research. Have sex in the first ten days. Manipulate again after episiotomy repair. Have a 3rd and 4th grade tear of the perineum Have postpartum fever. Childbirth with tools. The placenta should be removed by hand. There is a hematoma in the episiotomy area The first stage of labor is more than 14 hours, the second stage is more than 2 hours, and the third stage is more than one hour The baby should be admitted to the NICU

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Blocked random assignment In this study, permutation blocks method will be used to generate the sequence of random assignment of people to the studied groups. Random allocation sequence of people will be done using Random Allocation Software and block size of four. The permutation block method is one of the random allocation methods in which each block is selected according to the number of studied groups. In this study, there are six blocks AABB (1), ABAB (2), ABBA (3), BBAA (4), BABA (5) and BAAB (6). One of the blocks is randomly selected. If the first block, AABB, is selected, the first and second people are assigned to group A, and the third and fourth people are assigned to group B, and this process continues until all the samples are assigned. The characteristic of this method is that the two study groups will have equal numbers. Allocation Concealment method Random Allocation Software Sealed envelopes are used to hide the assignment. Based on the order of entry of the research units, the envelopes will be opened in order and the assigned group will be revealed. In order to hide the allocation, opaque envelopes numbered consecutively (in the order of allocation sequence) were used, which will contain 2 bottles containing the solution. Medicines will be placed in the envelopes based on the random sequence of allocation by a person not involved in the research. Entering people into the study and delivering the envelopes from number 1 to 120 will be done by the researcher himself

Blinding (investigator's opinion)

Triple blinded

Blinding description

The drug and placebo are blinded by the pharmacist and the researcher and the participants will not know the contents of the package. The desired cream is prepared in containers of one shape and one color of 30 grams, and coding (A, B) will be done on the containers by a pharmacist consultant. 38 participants in each group will receive cream A or B randomly.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Khorasan Razavi, Mashhad, University Street, Central Organization of Qurashi Building University

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2023-05-30, 1402/03/09

Ethics committee reference number
IR.MUMS.NURSE.REC.1402.032

Health conditions studied

1

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

2

Description of health condition studied
Episiotomy wound
ICD-10 code
070.0
ICD-10 code description
First degree perineal laceration during delivery

3

Description of health condition studied
Episiotomy wound
ICD-10 code
O70.1
ICD-10 code description
Second degree perineal laceration during delivery

Primary outcomes

1

Description
Reducing the pain intensity score at the episiotomy site based on the visual pain scale tool
Timepoint
The first, fifth and 10 to 14 days after delivery
Method of measurement
Visual tool for pain

2

Description
Reducing the redness score of the episiotomy wound based on the Rida tool
Timepoint
The first, fifth and 10 to 14 days after delivery
Method of measurement
Rida too

3

Description
Reduction of episiotomy wound edge edema score based on Rida tool
Timepoint
The first, fifth and 10 to 14 days after delivery
Method of measurement
Rida too

4

Description
Reduction of episiotomy wound bruising score based on Rida tool
Timepoint
The first, fifth and 10 to 14 days after delivery
Method of measurement
Rida too

5

Description
Reduction of episiotomy wound edge cohesion score based on Rida tool
Timepoint
The first, fifth and 10 to 14 days after delivery
Method of measurement
Rida too

6

Description
Reducing the episiotomy wound discharge score based on the Rida tool
Timepoint
The first, fifth and 10 to 14 days after delivery
Method of measurement
Rida too

7

Description
Wound healing based on the reduction of the mean total score of the Rida instrument
Timepoint
The first, fifth and 10 to 14 days after delivery
Method of measurement
Rida tool, observation of signs of infection (redness, secretion or purulent exudate, swelling of wound margin

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After random allocation, the intervention group received the cream containing 10% apricot kernel oil, which was prepared and filled in 30 gram tubes with code A or B under the supervision of professors of the Faculty of Pharmacy of Mashhad University of Medical Sciences (oil extraction with a cold press machine). Local face and every 12 hours, 2 cm of the product is consumed in the first 10 days after delivery
Category

Treatment - Drugs

2

Description
Control group: The control group will be placed in the placebo group after random allocation. The placebo is a standard cold cream without apricot kernel oil and as a simple cream base, which is similar to the drug in terms of shape and can only be distinguished by the code (by the pharmacist) and the method of use will be the same as the drug group

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Mashhad Hasheminejad Hospital

Full name of responsible person
Mahboobeh Firoozi

Street address
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2

Recruitment center

Name of recruitment center
Mashhad Umm al-Binin Hospital

Full name of responsible person
Mahboobeh Firoozi

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Faculty of Nursing and Midwifery, Ibn Sina Street, Doctor's Crossroad, University of Mashhad, Khorasan Razavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mahboobeh firoozi

Street address
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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Mahboobeh Firoozi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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Mahboobeh Firoozi
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Person responsible for updating data

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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