

# 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

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

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##### Email address

kharazmin4001@mums.ac.ir

##### 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

|                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
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| Investigating the effect of apricot kernel oil cream on pain intensity and episiotomy wound healing in primiparous women |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Public title</b>                                                                                                      | Investigating the effect of apricot kernel oil cream on pain and healing of episiotomy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Purpose</b>                                                                                                           | Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <b>Inclusion/Exclusion criteria</b>                                                                                      | <p><b>Inclusion criteria:</b><br/>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</p> <p><b>Exclusion criteria:</b><br/>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</p>                                                                                                     |
| <b>Age</b>                                                                                                               | From <b>18 years</b> old to <b>35 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Gender</b>                                                                                                            | Female                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Phase</b>                                                                                                             | 2-3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Groups that have been masked</b>                                                                                      | <ul style="list-style-type: none"> <li>• Participant</li> <li>• Care provider</li> <li>• Investigator</li> <li>• Outcome assessor</li> <li>• Data analyser</li> <li>• Data and Safety Monitoring Board</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Sample size</b>                                                                                                       | Target sample size: <b>76</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Randomization (investigator's opinion)</b>                                                                            | Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Randomization description</b>                                                                                         | 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 |
|                                                                                                                          | <b>Blinding (investigator's opinion)</b><br>Triple blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|                                                                                                                          | <b>Blinding description</b><br>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.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|                                                                                                                          | <b>Placebo</b><br>Used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|                                                                                                                          | <b>Assignment</b><br>Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                                                                                                          | <b>Other design features</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|                                                                                                                          | <b>Secondary Ids</b><br>empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                                                                                                                          | <b>Ethics committees</b><br><b>1</b><br><b>Ethics committee</b><br><b>Name of ethics committee</b><br>Ethics Committee of Mashhad University of Medical Sciences<br><b>Street address</b><br>Khorasan Razavi, Mashhad, University Street, Central Organization of Qurashi Building University<br><b>City</b><br>Mashhad<br><b>Province</b><br>Razavi Khorasan<br><b>Postal code</b><br>9138813944<br><b>Approval date</b><br>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

O70.0

#### 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

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**

At the end of Abu Rihan Boulevard, Shahid Muftah Boulevard, Tollab

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

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**Phone**

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**Email**

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2**Recruitment center****Name of recruitment center**

Mashhad Umm al-Binin Hospital

**Full name of responsible person**

Mahboobeh Firoozi

**Street address**

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

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Mashhad

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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**

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

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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

**Street address**

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

**City**

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## Person responsible for scientific 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**  
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## Person responsible for updating data

### 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  
**Street address**  
Faculty of Nursing and Midwifery, Ibn Sina Street,  
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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