

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### The effectiveness of olive and black seed oil combination in pain intensity and episiotomy wound healing in prim parous women referred to hospitals under the auspices of Babol University of Medical Sciences

#### Protocol summary

##### Study aim

Determining the effectiveness of olive and black seed oil combination in pain intensity and episiotomy wound healing in prim parous women referred to hospitals under the auspices of Babol University of Medical Sciences

##### Design

A clinical trial with 2 intervention and 1 control groups. 3 blind strains, 108 randomized samples with blocks of four and open label in three groups

##### Settings and conduct

The researcher will select and randomly assign the samples to two intervention groups and one routine care group according to the study entry criteria. Eligible people are placed in one of three groups A: 36 people, B: 36 people, and C: 36 people, using permuted block randomization and open label. The size of the blocks is 6 and in each block each intervention group will be repeated twice. 18 blocks of 6 will be produced to create a sequence of size 108. In order to hide the list of random allocation, a special code will be assigned to each of the intervention groups, which only the main implementer of the project will be aware of. Location: Hospitals covered by Aluk Medical University of Babol. People in the intervention group use a glass containing oils with a dose of 10 drops locally and 3 times a day 24 hours after delivery, for 10 days.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: primiparous women, normal delivery with episiotomy, having literacy, BMI <30. Exclusion criteria: lack of personal desire to continue the study, lack of regular use of oils, 4th degree tear, history of skin dermatitis, history of allergies and eczema to plants, history of gestational diabetes and obvious

##### Intervention groups

Two intervention groups receiving the combination of olive oil and black seed. Olive oil alone. Control group

receiving routine care

##### Main outcome variables

Episiotomy pain intensity, Episiotomy wound healing

#### General information

##### Reason for update

The impossibility of sampling in the initial forecast period due to the non-cooperation of some gynecologists

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180218038783N2**

Registration date: **2022-12-23, 1401/10/02**

Registration timing: **prospective**

Last update: **2023-12-29, 1402/10/08**

Update count: **1**

##### Registration date

2022-12-23, 1401/10/02

##### Registrant information

##### Name

Fereshteh Behmanesh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3219 0504

##### Email address

f.behmanesh@mubabol.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-05, 1401/11/16

##### Expected recruitment end date

2025-03-19, 1403/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effectiveness of olive and black seed oil combination in pain intensity and episiotomy wound healing in primiparous women referred to hospitals under the auspices of Babol University of Medical Sciences

**Public title**

The effectiveness of olive and black seed oil combination in pain intensity and episiotomy wound healing

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Primiparous women Normal delivery with episiotomy  
Having literacy BMI < 30

**Exclusion criteria:**

The personal unwillingness of the participants to continue the study, Women who do not use oils regularly.  
4th degree tear History of diagnosed skin dermatitis  
History of allergy and eczema diagnosed to plants  
History of gestational diabetes and obvious

**Age**

From **15 years** old to **45 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

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

**Sample size**

Target sample size: **108**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The researcher will select the samples according to the Inclusion criteria and assign them randomly (using the block randomized method) to two groups of intervention and routine care. Eligible people are placed in one of three groups A: 36 people, B: 36 people, and C: 36 people, using permuted block randomization and open label. The size of the blocks is 6 and in each block each intervention group will be repeated twice. 18 blocks of 6 will be produced to create a sequence of size 108.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

In order to hide the list of random allocation, a special code will be assigned to each of the intervention groups, which only the main executor of the project (supervisor) will be aware of. Also, the second moderator, who is a

student and evaluator of the study and the person who performs the statistical analysis, will not know about the codes assigned to the drugs.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Babol University of Medical Sciences

**Street address**

Mazandaran, Babol, Ganj Afrooz Street, Babol University of Medical Sciences

**City**

Babol

**Province**

Mazandaran

**Postal code**

4774547176

**Approval date**

2022-12-12, 1401/09/21

**Ethics committee reference number**

IR.MUBABOL.REC.1401.145

**Health conditions studied****1****Description of health condition studied**

Episiotomy pain intensity

**ICD-10 code**

G89

**ICD-10 code description**

Pain, not elsewhere classified

**2****Description of health condition studied**

Episiotomy wound repair

**ICD-10 code**

O86.0

**ICD-10 code description**

Infection of obstetric surgical wound

**Primary outcomes****1****Description**

The intensity of pain in the episiotomy area is based on the person's statements, where 0 means the least pain

and 10 means the most possible pain.

#### **Timepoint**

24 hours after delivery (before the start of the intervention) and on the 10th day after starting the topical use of oils

#### **Method of measurement**

10 cm pain ruler scale

## **2**

#### **Description**

Healing of episiotomy wound based on measuring the variables of swelling, bruising, redness and the distance between the two edges of episiotomy wound in lithotomy position.

#### **Timepoint**

24 hours after delivery (before the start of the intervention) and on the 10th day after starting the topical use of oils

#### **Method of measurement**

Episiotomy wound healing REEDA scale

## **Secondary outcomes**

### **1**

#### **Description**

Burning and itching

#### **Timepoint**

The first ten days after delivery

#### **Method of measurement**

Examination

### **2**

#### **Description**

Episiotomy opening

#### **Timepoint**

The first ten days after delivery

#### **Method of measurement**

Examination

### **3**

#### **Description**

The need for painkillers

#### **Timepoint**

The first ten days after delivery

#### **Method of measurement**

Examination

## **Intervention groups**

### **1**

#### **Description**

Intervention group 1: recipient of black seed oil and olive:All the subjects of the study will be taught how to follow the health tips after childbirth, and the samples of the intervention group will be taught how to use the container containing the oils. In such a way that they use the container containing black seed and olive oil with a

dose of 10 drops locally and three times a day 24 hours after giving birth, for 10 days. The researcher also examines the severity of perineal pain and healing of episiotomy wound in the first 24 hours after delivery and ten days after that.

#### **Category**

Treatment - Other

### **2**

#### **Description**

intervention group 2: Recipient of olive oil alone:All the subjects of the study will be taught how to follow the health tips after childbirth, and the samples of the intervention group will be taught how to use the container containing the oils. In such a way that they use a container containing olive oil with a dose of 10 drops locally and three times a day 24 hours after giving birth, for 10 days. The researcher also examines the severity of perineal pain and healing of episiotomy wound in the first 24 hours after delivery and ten days after that.

#### **Category**

Treatment - Other

### **3**

#### **Description**

Control group: They receive routine cares.

#### **Category**

N/A

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Babol University of Medical Sciences

##### **Full name of responsible person**

Fereshteh Behmanesh

##### **Street address**

Babol University of Medical Sciences, Keshavarz St, Babol, Mazandaran

##### **City**

Babol

##### **Province**

Mazandaran

##### **Postal code**

4717647745

##### **Phone**

+98 11 3219 9594

##### **Email**

f.behmanesh@mubabol.ac.ir

##### **Web page address**

<https://yahya.mubabol.ac.ir>

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Dr. Mehdi Rajab Nia

**Street address**

Ganj Afrooz Sreet, Babol University of Medical Sciences

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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**

Babol 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**

Babol University of Medical Sciences

**Full name of responsible person**

Fereshteh Behmanesh

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

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f.behmanesh2015@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Fereshteh Behmanesh

**Position**

Associated professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

**Full name of responsible person**

Fereshteh behmanesh

**Position**

Associate professor

**Latest degree**

Ph.D.

**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**

There is no further information.

**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**

Not applicable