

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Evaluation the effect of perineal massage with sweet almond oil in late pregnancy on perineal trauma in pregnant women

#### Protocol summary

##### Study aim

Determining the effect of perineal massage with sweet almond oil in late pregnancy on perineal trauma of pregnant women

##### Design

Randomized clinical trial The number of 120 pregnant women eligible to enter the study, will be divided into 3 groups of 40 people, based on randomization by a computer program, using random blocks of size 6. Intervention group 1 (massage with sweet almond oil), intervention group 2 (massage with paraffin) and control group (routine care) will receive.

##### Settings and conduct

pregnant women eligible to the study by the available method. The number of samples will be 120 mothers and the allocation of samples will be in blocks. Intervention group 1 (massage with sweet almond oil), intervention group 2 (massage with paraffin) and control group (routine care) will receive. Pregnant women in intervention groups from 34 weeks will be delivered coded bottles containing oil and both groups will be taught how to massage the perineum. All participants will be evaluated for the degree of perineal tear and episiotomy during delivery. Data will be analyzed after collection using SPSS version 24 software. The significance level in the tests will be considered 0.05.

##### Participants/Inclusion and exclusion criteria

All Iranian pregnant women who are at the end of their pregnancy

##### Intervention groups

massage group with sweet almond oil, massage group with paraffin and control group

##### Main outcome variables

The state of perineal trauma

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20230226057540N1**

Registration date: **2023-05-27, 1402/03/06**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-05-27, 1402/03/06**

Update count: **0**

#### Registration date

2023-05-27, 1402/03/06

#### Registrant information

##### Name

Maryam Mohseni khalilabadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3428 9767

##### Email address

mohseni\_2007@yahoo.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2023-03-10, 1401/12/19

#### Expected recruitment end date

2023-09-21, 1402/06/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation the effect of perineal massage with sweet almond oil in late pregnancy on perineal trauma in pregnant women

## Public title

Evaluation the effect of perineal massage with sweet almond oil in late pregnancy on perineal trauma

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

pregnancy Iranian nationality

### Exclusion criteria:

Multiple births women aged less than 18 and more than 35 years Gestational age more than 35 weeks Malpresentation and Malposition Unwillingness to have a vaginal birth History of cesarean section Estimated fetal weight is less than 2500 and more than 4000 g

## Age

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

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **120**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Women eligible to enter the study will be divided into 3 groups of 40 people based on randomization by the CREATE A RANDOMISATION LIST program, using random blocks of size 6. The output of the software will be random letters (c, b, a) and each letter belongs to one of the intervention and control groups with the same probability 2 times in each block. In this study, 20 blocks of 6 are used, the first 6 people will be placed in three groups completely randomly (allocation of 2 people to each of the groups), then the next 6 people will be studied in three groups in the same way. The method will continue until the 6th person. The program CREATE A RANDOMISATION LIST can be retrieved on the Internet at <https://www.sealedenvelope.com/simple-randomiser/v1/lists>

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Sweet almond oil and paraffin prepared in Barij Esans Company are distributed to mothers in similar jars marked with code A and B. The midwife responsible for the delivery does not know the type of massage oil in the groups. The statistical consultant who is in charge of data analysis is not aware of the type of oil in groups A and B.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Rafsanjan University of Medical Sciences

##### Street address

Department of Midwifery, Faculty of Nursing and Midwifery , Nurse st.

##### City

Rafsanjan

##### Province

Kerman

##### Postal code

7718796755

#### Approval date

2023-02-18, 1401/11/29

#### Ethics committee reference number

IR.RUMS.REC.1401.218

## Health conditions studied

### 1

#### Description of health condition studied

The state of perineal trauma

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

perineal trauma

#### Timepoint

during childbirth

#### Method of measurement

check list

### 2

#### Description

Episiotomy

#### Timepoint

during childbirth

#### Method of measurement

check list

### 3

#### Description

Apgar score

#### Timepoint

After childbirth

#### Method of measurement

Number

#### 4

##### **Description**

The length of the first stage of labor

##### **Timepoint**

during childbirth

##### **Method of measurement**

Number of hours

#### 5

##### **Description**

The length of the second stage of labor

##### **Timepoint**

during childbirth

##### **Method of measurement**

Number of hours

## **Secondary outcomes**

empty

## **Intervention groups**

#### 1

##### **Description**

Intervention group: Perineum massage with 1 cc of sweet almond oil will be performed daily for 10 minutes from the 34th week of pregnancy until delivery. Bottles of sweet almond oil and paraffin will be prepared by Barij Esans Company in similar packages that are marked with a code.

##### **Category**

Prevention

#### 2

##### **Description**

Intervention group: Perineum massage with 1 cc of paraffin oil will be performed daily for 10 minutes from the 34th week of pregnancy until delivery.

##### **Category**

N/A

#### 3

##### **Description**

Control group: No intervention

##### **Category**

N/A

## **Recruitment centers**

#### 1

##### **Recruitment center**

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

Comprehensive health centers in Rafsanjan

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

Masoume Sahibi

##### **Street address**

Department of Midwifery, Faculty of Nursing and Midwifery, Nurse st.

##### **City**

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##### **Postal code**

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##### **Phone**

+98 34 3425 5900

##### **Email**

mohseni\_2007@yahoo.com

## **Sponsors / Funding sources**

#### 1

##### **Sponsor**

###### **Name of organization / entity**

Rafsanjan University of Medical Sciences

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

Dr. Reza Vazirinejad

###### **Street address**

Department of Midwifery, Faculty of Nursing and Midwifery, Nurse st.

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###### **Province**

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###### **Email**

mohseni\_2007@yahoo.com

##### **Grant name**

##### **Grant code / Reference number**

##### **Is the source of funding the same sponsor organization/entity?**

Yes

##### **Title of funding source**

Rafsanjan 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**

Rafsanjan University of Medical Sciences

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

Maryam Mohseni khalilabadi

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

No.9, Alley 7, Pezeshk Ave., DehghanRajabi 3 st.  
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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Person responsible for updating data****Contact****Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

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**Postal code**

7717936903

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**Fax****Email**

mohseni\_2007@yahoo.com

**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**

Not applicable

**Data Dictionary**

Not applicable