

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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Reza Vazirinejad

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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

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

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Latest degree

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Other areas of specialty/work

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

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Full name of responsible person

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Position

Assistant Professor

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Fax**Email**

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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

Not applicable

Data Dictionary

Not applicable