Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 parafin 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.
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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
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Person responsible for updating data

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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