Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

The effect of sweet almond oil vaginal suppository on the ripening of the cervix in primiparous women

Protocol summary

Study aim
The effect of sweet almond oil vaginal suppository on the ripening of the cervix in primiparous women

Design
The clinical trial has a control group, three blind strains with parallel and randomized groups. 66 mothers with 40 weeks of pregnancy are selected as primary and available samples and are placed in two intervention and control groups using simple random allocation on the web by the sequence created on the website www.randomizer.org.

Settings and conduct
The units will be selected among the mothers referring to the obstetric clinic of Umm al-Binin Hospital (S) and Shahid Hashminejad Hospital of Mashhad. According to the intervention or control group, the units use one vaginal suppository sweet almond oil 20% or placebo for 7 nights before going to bed. Both groups will be advised to visit the clinic 72 hours and one week after the start of the study in order to control and determine the Bishop's score if labor pains do not start. If labor pains do not start at the beginning of the 41st week, they will be admitted to the maternity hospital to terminate the pregnancy. People's codes are kept in closed envelopes for confidentiality.

Participants/Inclusion and exclusion criteria
conditions for entering : primiparous, maternal age between 18-35, gestational age 40 weeks, singleton pregnancy, cephalic fetal presentation, non-drug dependence, maternal body mass index in the range of18.5_30, Bishop's score of 6 or less, non-reactive stress test, impact water bag. conditions of not entering the study before randomization: allergy to sweet almond oil, medical and obstetric problems.

Intervention groups
The units of the intervention group use a vaginal suppository of sweet almond oil for 7 nights, and the units of the control group use a placebo for 7 nights. The consumption of these suppositories in both groups starts from 40 weeks of pregnancy.

Main outcome variables
Ripening of the cervix

General information

Reason for update
recording of the actual patient recruitment start and end dates.

Acronym

IRCT registration information
IRCT registration number: **IRCT20230526058296N1**
Registration date: **2023-07-12, 1402/04/21**
Registration timing: **prospective**

Last update: **2026-06-06, 1405/03/16**
Update count: **1**

Registration date
2023-07-12, 1402/04/21

Registrant information

Name
Parisa Hosseini

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 903 832 2464

Email address
hoseinibp4001@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-27, 1402/04/06

Expected recruitment end date
2024-07-21, 1403/04/31

Actual recruitment start date

2023-07-19, 1402/04/28

Actual recruitment end date

2024-01-30, 1402/11/10

Trial completion date

empty

Scientific title

The effect of sweet almond oil vaginal suppository on the ripening of the cervix in primiparous women

Public title

The effect of sweet almond oil vaginal suppository on the ripening of the cervix

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

primiparous women 18 to 35 years Gestational age 40 weeks Singleton pregnancy Cephalic presentation Body mass index 18.5 to 30 Intact fetal membranes no drug addiction Bishop score 6 or less Reactive non-stress test

Exclusion criteria:

Sensitivity to sweet almond oil Medical and obstetric problems

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **66**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The cases are selected as available and the allocation of eligible pregnant women to the intervention and control groups will be done randomly and with a random sequence created by the website www.randomizer.org. These sequences are produced as quadruple blocks with equal number of A and B (coded by A and B).

Blinding (investigator's opinion)

Triple blinded

Blinding description

The drug and placebo are blinded by the pharmacist. The researcher and the participants will not know the contents of the package. The desired suppositories will be prepared in the same size and color with a weight of 3 grams, and the coding on the envelopes (A and B) will be done by the pharmacist consultant. 33 participants in each group will randomly receive suppositories A or B.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Assistance of Research and Technology of Mashhad University of Medical Sciences, Qurashi building, Daneshgah avenue

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2023-06-06, 1402/03/16

Ethics committee reference number

IR.MUMS.NURSE.REC.1402.029

Health conditions studied

1

Description of health condition studied

Ripening of the cervix

ICD-10 code

O80.0

ICD-10 code description

Spontaneous vertex delivery

Primary outcomes

1

Description

Ripening of the cervix

Timepoint

Before intervention,3 days,1 week after intervation and at the time of hospitalization

Method of measurement

Examination

Secondary outcomes

1

Description

onset of labor

Timepoint

Before intervention,3 days,1 week after intervation and at the time of hospitalization

Method of measurement

Examination

Intervention groups

1

Description
Intervention group: The intervention group uses one 20% sweet almond oil vaginal suppository every night before going to bed for 7 days after determining Bishop's score from the 40th week of pregnancy. If labor does not start, refer three days and one week later to determine Bishop's score and perform a non-stress test (NST). If the labor does not start until the 41st week, the mother will be referred to the maternity hospital to terminate the pregnancy.

Category
Other

2

Description
Control group: The control group uses a placebo every night before going to bed for 7 days after determining Bishop's score from the 40th week of pregnancy. If labor does not start, refer three days and one week later to determine Bishop's score and perform a non-stress test (NST). If the labor does not start until the 41st week, the mother will be referred to the maternity hospital to terminate the pregnancy.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Omolbanin hospital

Full name of responsible person
Doctor Masoumeh Mirteymouri

Street address
Omolbanin hospital,16th Bahjat street, Ayatollah Bahjat avenue, Mashhad, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9177899191

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Email
MirteimouriM@mums.ac.ir

Web page address
https://woman.mums.ac.ir/

2

Recruitment center

Name of recruitment center
Shahid Hashemi-nejad Hospital

Full name of responsible person
Doctor seyed Mohammad Moosavi

Street address
Shahid Hashemi Nezhad Hospital, Tolab, Shahid Mofateh Avenue, end of Abooreihan Boulevard

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1234567

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Mosavim3@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Doctor Mohammad Ali Kiani

Street address
School of Nursing and Midwifery,Doctora Crossroads,Daneshgah Street

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Mashhad

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Postal code
9137913199

Phone
+98 51 3859 1511

Email
mohammadis992@mums.ac.ir

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

Parisa Hosseini Balajourshari

Position

master student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery,Doktora Crossroads, Daneshgah Street

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Phone

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Email

Hoseinibp4001@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Fatemeh zahra karimi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Email

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Parisa Hosseini Balajourshari

Position

master student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery,Doktora Crossroads, Daneshgah Street

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Province

Razavi Khorasan

Postal code

9137913199

Phone

+98 51 3859 1511

Email

Hoseinibp4001@mums.ac.ir

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