Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of vaginal consumption of primrose oil on the preparation of cervix in term delivery at patient resort to educational hospitals of Medical Sciences

Protocol summary

Study aim
Determining the effect of vaginal consumption of evening primrose oil on cervical preparation in women referred to hospitals of Mashhad University of Medical Sciences

Design
The clinical trial has a control group, with parallel groups, non-blinding, randomized, phase 1 on 76 pregnant women with a full gestational age of 40 weeks. For randomization, a simple randomization divided by days of the week will be used.

Settings and conduct
This study will be performed on a group of women referring to Imam Reza (AS) Hospital in Mashhad. The outcome assessors are unaware of the allocation group and using codes A and B instead of group names.

Participants/Inclusion and exclusion criteria
This study will be performed on a group of women referred due to ethical considerations of without any blinding. Prior to entering the study, participants will receive an informed consent form attached to this study.

Intervention groups
Evening primrose oil capsules will receive up to 6 doses vaginally every 4 to 6 hours a day. In the control group, only the initial examination is performed.

Main outcome variables
Bishop overall score, subgroups of this scoring system

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201115049389N1**
Registration date: **2021-01-16, 1399/10/27**
Registration timing: **registered_while_recruiting**
Last update: **2021-01-16, 1399/10/27**
Update count: **0**

Registration date
2021-01-16, 1399/10/27

Registrant information

Name
Mahya Labbafchi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3802 2608

Email address
labbafchimahya@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-09, 1399/08/19

Expected recruitment end date
2021-10-31, 1400/08/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of vaginal consumption of primrose oil on the preparation of cervix in term delivery at patient resort to educational hospitals of Medical Sciences

Public title
Comparison of the effect of vaginal consumption of primrose oil on the preparation of cervix in term delivery

at patient resort to educational hospitals of Medical Sciences

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Low risk of pregnancy Bishop score less than 4 BMI between 19 and 25 Lack of systemic disease No drug addiction No vaginal bleeding Gain conscious satisfaction

Exclusion criteria:

Patient non-cooperation Increased risks of delivery Use other methods of uterine preparation Diabetes and hypertension Chronic inflammatory disease Improper fetal presentation

Age

No age limit

Gender

Female

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Since the two groups are supposed to have the same sample size, Patients eligible for inclusion will be divided into 2 groups using the Blocked Randomization method by one of the nurses of the relevant ward, who is not aware of the implementation of the study. Random sequences will be generated using the Random Generator program. Random allocation concealment will be done using sequentially numbered, sealed, opaque envelopes by an independent person who does not know the study process.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

529 / 5000Translation resultsWe use the Bishop score to check the degree of softening of the cervix. We randomly divide the referring women into two groups, A and B, after completing the informed consent form. We measure demographic information, gestational age, bishop score, last period date, induction delivery interval, mode of delivery, 3rd stage blood loss, and fetomaternal outcome. In both groups, strip is done and one group of primrose oil is blinded on one side. We measure Bishop score, duration of labor, and postpartum hemorrhage, Apgar score 1 and 5 minutes.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Department of Obstetrics and Gynecology, Imam Reza Hospital, Taghiabad Square

City

Mashhad

Province

Razavi Khorasan

Postal code

91388-13944

Approval date

2020-11-09, 1399/08/19

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.459

Health conditions studied

1

Description of health condition studied

Pregnant mothers

ICD-10 code

P03.8

ICD-10 code description

Newborn (suspected to be) affected by other specified complications of labor and delivery

Primary outcomes

1

Description

Bishop score measured

Timepoint

Before interventional and 24 hours after intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Evening primrose oil capsules will receive up to 6 doses vaginally every 4 to 6 hours a day.

Category

Treatment - Drugs

2

Description

Control group: They are just examined.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Marzieh Lotfalizadeh

Street address

Department of Obstetrics and Gynecology, Imam Reza Hospital, Taghiabad Square.

City

Mashhad

Province

Razavi Khorasan

Postal code

91766-99199

Phone

+98 51 3801 2469

Email

lotfalizadem@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Qoreighi Building, Daneshgah Street.

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Phone

+98 51 3841 1538

Email

vcresearch@mums.ac.ir

Grant name

Marzieh Lotfalizadeh

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

Marzieh Lotfalizadeh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Imam Reza hospital. Imam Reza square.

City

Mashhad

Province

Razavi Khorasan

Postal code

91766-99199

Phone

+98 51 3854 3031

Email

lotfalizade@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mahya Labbafchi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Imam Reza hospital. Imam Reza square.

City

Mashhad

Province

Razavi Khorasan

Postal code

91766-99199

Phone

+98 51 3854 3031

Email

LabbafchiM961@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mahya Labafchi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Imam Reza hospital. Imam Reza square.
City
Mashhad
Province
Razavi Khorasan
Postal code
91766-99199
Phone
+98 51 3854 3031
Email
LabbafchiM961@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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable