

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of the effect of vaginal misoprostol alone and in combination with Evening primrose Capsule on the state of delivery in pregnant women candidate for pregnancy termination

Protocol summary

Study aim

Comparison of the effect of vaginal mesoprostol alone and in combination with Evening primrose Capsule on the state of delivery in pregnant women candidate for pregnancy termination

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, on 30 nulliparous and multiparous pregnant women, simple randomization with sealed envelope, analysis with SPSS with statistical methods

Settings and conduct

Double-blind randomized clinical trial, the effect of vaginal mesoprostol and evening primrose on the course of delivery of 30 nulliparous and multiparous pregnant women with a gestational age of 38-42 weeks. The mothers will be selected in two categories A and B. The researcher will calculate the bishop score and record the duration of the latent and active phase of labor, type of labor, neonatal Apgar score and postpartum hemorrhage volume and pain intensity in both groups. Participants, clinical caregivers, outcome assessors, data analysts will not know the type of drug used.

Participants/Inclusion and exclusion criteria

Input: Single pregnancy live fetus Fetal weight less than 4 kg Amniotic fluid index more than 5 cm normal fetus NST Bishop score less than 7 Absence of labor pains in the mother Exit : Rupture of membranes Possibility of fetal abnormalities need for urgent delivery Hypersensitivity to prostaglandins and evening primrose History of seizures history of schizophrenia with phenothiazin Prescription Bleeding disorders or taking anticoagulants Fallen in FHR Malpresentation Fetal disorders such as hydrocephalia

Intervention groups

Group A (1000 mg vaginal capsule of evening primrose with the use of 25 µg vaginal mesoprostol by Pfizer)

Group B (vaginal medication and vaginal mesoprostol tablets)

Main outcome variables

Pain, bleeding, dilatation of the cervix

General information

Reason for update

Acronym

m_epc

IRCT registration information

IRCT registration number: **IRCT20210113050028N2**

Registration date: **2022-05-01, 1401/02/11**

Registration timing: **prospective**

Last update: **2022-05-01, 1401/02/11**

Update count: **0**

Registration date

2022-05-01, 1401/02/11

Registrant information

Name

Noushin Mobaraki-asl

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3323 5861

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-21, 1401/02/31

Expected recruitment end date

2022-07-22, 1401/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of vaginal misoprostol alone and in combination with Evening primrose Capsule on the state of delivery in pregnant women candidate for pregnancy termination

Public title

Comparison of the effect of vaginal misoprostol and Evening primrose Capsule on the state of delivery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Single pregnancy live fetus Fetal weight less than 4 kg Amniotic fluid index more than 5 cm normal fetus NST Bishop score less than 7 Absence of labor pains in the mother

Exclusion criteria:

Rupture of membranes Possibility of fetal abnormalities need for urgent delivery Hypersensitivity to prostaglandins and evening primrose History of seizures history of schizophrenia with phenothiazin Prescription Bleeding disorders or taking anticoagulants Fallen in FHR Malpresentation Fetal disorders such as hydrocephalia

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided randomly. By preparing 30 packets, 15 packets of group A (1000 mg vaginal capsule of evening primrose with 25 µg of Pfizer vaginal mesoprostol) and 15 packets of group B containing vaginal suppositories and vaginal mesoprostol tablets. Every pregnant woman will give one of the envelopes to the researcher by lot to perform delivery induction for the pregnant woman. The researcher will record all the information by attending the mothers' bedside.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient receives the drug (misoprostol group and evening primrose group) in sealed packets that are

encoded. The coding is done by one of the project partners and the participant, clinical caregiver, outcome assessor, data analyzer will not know the type of drug used.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in Biomedical Research, Ardabil University of Medical Sciences

Street address

End of Daneshgah St., Administrative Complex of Ardabil University of Medical Sciences

City

Ardabil

Province

Ardabil

Postal code

۵۶۱۸۹-۸۵۹۹۱

Approval date

2021-03-07, 1399/12/17

Ethics committee reference number

IR.ARUMS.REC.1400.023

Health conditions studied**1****Description of health condition studied**

Normal Vaginal Delivery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

amount of pain

Timepoint

Pain measurement scale based on counting between two contractions

Method of measurement

Pain scale: The amount of pain between zero no pain and 10 most severe pain possible

2**Description**

Vaginal bleeding

Timepoint

During labor

Method of measurement

The amount of vaginal bleeding

3

Description

infant Weight

Timepoint

After birth

Method of measurement

Weighing the baby

4

Description

Infant APGAR

Timepoint

0-5-10 minutes after birth

Method of measurement

According to the standard Apgar score of infants

5

Description

Latent & active phase duration

Timepoint

From the onset of labor symptoms to the end of the active phase

Method of measurement

Latent & active phase duration

6

Description

Cervical dilatation

Timepoint

0-10 cm

Method of measurement

Induction of cervical dilatation before and after

Secondary outcomes

1

Description

Duration of latent phase of labor

Timepoint

from the beginning of contractions to dilatation 3-6 cm

Method of measurement

Vaginal examination

2

Description

Active phase of labor

Timepoint

From dilatation of 3-6 cm to the birth of a baby

Method of measurement

Vaginal examination

3

Description

method of delivery

Timepoint

Decide on the method of termination of labor

Method of measurement

Termination method of pregnancy

4

Description

The volume of postpartum hemorrhage

Timepoint

Until the end of the labor phase

Method of measurement

Number of bloody pads

5

Description

Pain intensity

Timepoint

every 30 minutes to 2 hours

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group: Receiving 1000 mg vaginal capsule of evening primrose with the use of 25 µg vaginal mesopozostol by Pfizer

Category

Treatment - Drugs

2

Description

Control group: Vaginal view medication and vaginal mesoprostol tablets

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi Hospital

Full name of responsible person

Nooshin Mobaraki_asl

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ardabil University of Medical Sciences
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Farhad Pourfarzi - Vice Chancellor for Research
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Grant name

-

Grant code / Reference number

-

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

No

Title of funding source

Dr. Shahrzad Gorbani(researcher)

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Noushin Mobaraki-asl
Position
Assistant professor of Oncology
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data and results will be published as article

When the data will become available and for how long

After completing the research

To whom data/document is available

researchers

Under which criteria data/document could be used

To help spread science

From where data/document is obtainable

Dr. Nooshin Mobaraki_asl

What processes are involved for a request to access data/document

reference article

Comments