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
]nput: 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 mesopzostol 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)

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+98 45 3323 5861

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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 mesopzostol) 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
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Postal code
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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 mesopzostol 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
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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
Gynecology and Obstetrics
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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