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
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Iran (Islamic Republic of)
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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
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

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

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
03189-82991

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 mesoprostol 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

**Street address**
Ardabil

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Farhad Pourfarzi - Vice Chancellor for Research
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End of Daneshgah St., Administrative Complex of Ardabil University of Medical Sciences
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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 updating data

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Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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n.mobaraki@arums.ac.ir

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