Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparison of vaginal misoprostol and vaginal evening primrose oil in first trimester termination

Protocol summary

Study aim
Comparison of the effect of vaginal mizemprostol and evening primrose oil in terminating pregnancy in the first trimester of pregnancy up to 14 weeks

Design
Clinical trial, with parallel groups, simple randomized, on 72 patients.

Settings and conduct
First, to all pregnant patients who refer to Shahid Beheshti Hospital for termination of pregnancy in the first trimester to 14 weeks and are candidates for termination of pregnancy due to Legal Abortion, Missed Abortion, Heart failure, Genetic anomalies. Complete explanations on how to perform them for the patient. It is explained, then the patient's consent to work is obtained, which is attached to the file.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Pregnant women go to Beheshti Hospital for up to 14 weeks to terminate their pregnancy for the reasons mentioned. Exclusion criteria: Uncontrolled seizures, uncontrolled blood pressure, chronic lung disease, mitral valve stenosis, history of known prostaglandin E1 allergy

Intervention groups
Vaginal misoprostol and vaginal evening primrose oil are divided into two groups. To a group of prostaglandin E1 (misoprostol) made in Iran, the active ingredient of which is 200 micrograms. Initial dose Initially 600 micrograms (three pills 200 micrograms) The next doses, if needed at intervals of 6 hours, repeat two vaginal pills with a maximum dose of 6 pills. To the second group, 1000 mg vaginal capsule of evening primrose oil in the posterior fornix of the vagina, which is repeated 1000 mg six hours later. Vaginal capsule of evening primrose from Barij company made in Iran

Main outcome variables
Number of misoprostol tablets prescribed and number of soft gels of evening primrose oil, uterine and fetal abnormalities, placental retention, time interval to excretion of products, fever complication

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201218049749N1**
Registration date: **2021-02-05, 1399/11/17**
Registration timing: **retrospective**

Last update: **2021-02-05, 1399/11/17**
Update count: **0**

Registration date
2021-02-05, 1399/11/17

Registrant information

Name
Maryam Mousavi Shirazi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 5550 0111

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-23, 1398/05/01

Expected recruitment end date
2019-10-23, 1398/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
A comparison of vaginal misoprostol and vaginal evening primrose oil in first trimester termination

Public title
A comparison of vaginal misoprostol and vaginal evening primrose oil

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women go to Beheshti Hospital for up to 14 weeks to terminate their pregnancy

Exclusion criteria:
Uncontrolled seizures Uncontrolled blood pressure Chronic lung disease Mitral valve stenosis History of known allergy to prostaglandin E1 Inflammatory bowel disease Sensitivity to evening primrose Coagulation disease Schizophrenia and phenothiazine use Cone biopsy of the cervix Smoking and supplements

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Block random, individual and using a table of random numbers were divided into two groups. Patients are completely randomly divided into two groups: vaginal misoprostol and vaginal evening primrose oil. In this method, a number of cards or letters selected by the researcher as the first group and the same number of cards for the next groups are considered; Then, by merging the cards together (flipping the cards), a card is taken out and its allocation is recorded, and that card is returned to the other cards after being taken out. The cards are then merged again and another card is removed. This process continues until a random sequence according to the sample size is reached.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kashan University of Medical Sciences

Street address
Qutb Ravandi Boulevard, Nursing Boulevard, School of Nursing and Midwifery

City
Kashan

Province
Isfehan

Postal code
8715988141

Approval date
2020-11-11, 1399/08/21

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1399.142

Health conditions studied

1

Description of health condition studied
Spontaneous abortion

ICD-10 code
O03.0

ICD-10 code description
Genital tract and pelvic infection following incomplete spontaneous abortion

Primary outcomes

1

Description
Spontaneous abortion

Timepoint
First and 6 hours and 12 hours after taking the drug

Method of measurement
Complete disposal of pregnancy products

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group : The effect of vaginal misoprostol, with Iranian brand and made in Iran, whose effective ingredient is 200 micrograms. Initial dose Initially 600 micrograms (three pills 200 micrograms) The next doses, if needed at intervals of 6 hours, repeat two vaginal pills with a maximum dose of 6 pills.

Category
Treatment - Drugs

2

Description
Second intervention group: The effect of vaginal evening primrose oil, with Barij brand of essential oil and made in Iran, with a dose of 1000 mg in the posterior vagina fornix, which is repeated six hours after 1000 mg.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital, Kashan

Full name of responsible person
Fatemeh Foroozan Fard

Street address
Qotb Ravandi Boulevard-Nurse Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
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Grant name

Grant code / Reference number

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

Title of funding source
Kashan 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
Kashan University of Medical Sciences

Full name of responsible person
Maryam Mousavi Shirazi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
General Practitioner

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Person responsible for scientific inquiries

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Position
Non-faculty specialist physician

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Specialist

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Person responsible for updating data

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Latest degree
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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
No - There is not 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
Part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long
Access period starts from 2020

To whom data/document is available
Researchers working in academic institutions

Under which criteria data/document could be used
To review and study more information

From where data/document is obtainable
Mail address

What processes are involved for a request to access data/document
The request will be sent by e-mail with the address and details of the researcher, after review, to the e-mail address of the requesting information.

Comments