Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of the effect of vaginal misoprostol and evening primrose oil capsules with misoprostol alone on the consequences of abortion in women with intrauterine fetal death

Protocol summary

Study aim
Comparison of the effect of vaginal misoprostol and evening primrose oil capsules with misoprostol alone on the consequences of abortion in women with intrauterine fetal death.

Design
Two-group, Triple-blind randomized clinical trial

Settings and conduct
This study will be performed on 84 women candidates for abortion due to intrauterine death of the fetus in Kamali Hospital. The primary outcome is the meantime from the start of the intervention to the abortion. The secondary consequence of the average dose of misoprostol is the highest pain intensity, the frequency of the number of people in need of blood transfusion, curettage and the frequency of side effects of drugs.

Participants/Inclusion and exclusion criteria
Iranian nationality, Married, Older and equal to 18 years, Gestational age 12 to 20 weeks, Having a single fetus according to ultrasound confirmation, Initial bishop score less than four, BMI less than 30, Indication of termination of pregnancy due to intrauterine death of the fetus with confirmation two ultrasounds, Drugs abuse and smoking more than ten cigarettes a day, History of cesarean section, contraindications to the use of evening primrose, Maternal medical disorders, Previously known drug allergy to misoprostol, Evening capsule vaginal capsule for two weeks continuous, Severe vaginal bleeding, Enema, Having a history of unsuccessful pregnancy, History of using any herbal and chemical drugs to help abortion before admission, Contraindications to the use of misoprostol.

Intervention groups
One group vaginally takes a dose of 200 micrograms of misoprostol tablets with a 1000 mg capsule of evening primrose oil up to five doses every 4 hours. The other group is in exactly the same way, except that the placebo takes evening primrose oil.

Main outcome variables
The mean duration from the beginning of the intervention to the abortion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181207041873N3**
Registration date: **2021-02-16, 1399/11/28**
Registration timing: **prospective**

Last update: **2021-02-16, 1399/11/28**
Update count: **0**

Registration date
2021-02-16, 1399/11/28

Registrant information

Name
Seyedeh Batool Hasanpoor-Azghady

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2286 0021

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hasanpoor.sb@iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-10, 1399/12/20

Expected recruitment end date
2021-09-06, 1400/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of vaginal misoprostol and evening primrose oil capsules with misoprostol alone on the consequences of abortion in women with intrauterine fetal death

Public title

Comparison of the effect of vaginal misoprostol and evening primrose oil capsules with misoprostol alone on the consequences of abortion in women with intrauterine fetal death

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian nationality Married Older and equal to 18 years Gestational age 12 to 20 weeks Having a single fetus according to ultrasound confirmation Initial bishop score less than four BMI less than 30 Indication of termination of pregnancy due to intrauterine death of the fetus with confirmation two ultrasounds

Exclusion criteria:

Drugs abuse smoking more than ten cigarettes a day History of cesarean section Contraindications to the use of evening primrose include: history of mental illness with phenothiazine, history of epilepsy, schizophrenia, history of bleeding disorders and use of anticoagulants Medical disorders in the mother such as heart disease, lung disease, active liver disease, acute hepatitis Previously known drug allergies to misoprostol include drowsiness, tremors, seizures, shortness of breath, hypotension, and bradycardia (WWW.Drugs.com) Medicinal allergies to evening primrose, including urticaria, wheezing, facial edema, lips, tongue and throat (WWW.Drugs.com) Severe anemia Having cervical anomalies Evening capsule vaginal capsule for two weeks continuous Severe vaginal bleeding Enema Having a history of unsuccessful pregnancy History of using any herbal and chemical drugs to help abortion before admission Contraindications to misoprostol use include: ectopic pregnancy, use of estrodiol-free drugs, symptoms of pelvic infection or sepsis, unstable hemodynamic status, mitral stenosis, glaucoma, asthma, bronchitis

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

The site https://www.sealedenvelope.com is used for random assignment of people in two groups by four-block size, concealment and blinding.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The present study is designed for triple-blind. 1000 mg capsules of evening primrose oil and its placebo are prepared by Darogster Barij Essential Oil Company and are made with specific codes A and B and are completely similar. The contents of the capsule are paraffin. The only pharmacist from the medicinal content of evening primrose oil capsules is known and the patient, researcher and assistant researcher and data analysts, outcome assessors, medical staff are unaware of this content.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committees of Iran University of Medical Sciences

Street address

Hemat Highway next to Milad Tower,Iran University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2021-01-12, 1399/10/23

Ethics committee reference number

IR.IUMS.REC.1399.1106

Health conditions studied

1

Description of health condition studied

the consequences of abortion in women with intrauterine fetal death

ICD-10 code

O04.9

ICD-10 code description
Medical abortion : complete or unspecified, without complication

Primary outcomes

1

Description
Mean duration from the beginning of the intervention to embryo expulsion
Timepoint
Beginning of the intervention to embryo expulsion
Method of measurement
Minute

Secondary outcomes

1

Description
The mean dose of misoprostol
Timepoint
End of intervention
Method of measurement
Microgram

2

Description
Intensity of pain
Timepoint
End of intervention
Method of measurement
Visual Analogue Scale-VAS

3

Description
People in need of blood transfusions
Timepoint
Blood transfusion time
Method of measurement
Frequency

4

Description
People in need of curettage
Timepoint
End of intervention
Method of measurement
Frequency

5

Description
Side effects of medications (fever, nausea, vomiting, diarrhea, chills)
Timepoint
From the beginning of the intervention until one hour after the fetus is expelled
Method of measurement
Frequency

Intervention groups

1

Description
The recommended dose of misogyny with FIGO protocol for termination of pregnancy due to intrauterine fetal death is 200 µg vaginal every four hours for a maximum of five doses. For the vaginal misoprostol group with evening primrose oil capsules, a dose of 200 micrograms misoprostol tablets with one 1000 mg evening primrose oil capsule is inserted vaginally up to five doses every 4 hours by a researcher or assistant researcher in the posterior fornix. Before placement, for faster absorption, moisten with 0.9% saline with 2 drops of normal saline and then placement. The clients are also told to place the drugs on the left side 30 minutes after placement. During the period of hospitalization from the time of intervention to the time of fetal and placental abruption, once every four hours and in the first hour after embryo and placenta every half an hour, vital signs of the mother, vaginal bleeding and side effects of drugs are recorded. If necessary, medical treatment is used to eliminate side effects. After the fetus is removed, an oxytocin infusion is given to help expel the placenta, and if the placenta does not come out within an hour or there is heavy bleeding at any stage, the patient becomes a candidate for curettage. Ultrasound is done through the vagina to check for pregnancy residues. The patient's hemoglobin is measured at the time of admission and six hours after the abortion. Pain intensity is measured twice. The first time is before the intervention when the specimens are admitted to the ward, and the second time is after the fetus is expelled. The mother is asked to identify the most pain they had in the period from the beginning of the intervention to the abortion on a visual analog scale. In this study, evening primrose oil capsule and its placebo are made by Daroo Gostar Barij Essential Oil Company. The misoprostol (Cytotec) tablet used in this study is made by of Iran Pharmaceutical Company. The dose of each tablet is 200 micrograms.
Category
Treatment - Drugs

2

Description
In the vaginal misoprostol group alone, it works exactly like the comparison group, except that the placebo of the evening primrose capsule, which is 1000 mg of paraffin and is quite similar to the real drug, is used.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Kamali Alborz Hospital
Full name of responsible person
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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?
Yes
Title of funding source
Iran University of Medical Sciences
Proportion provided by this source
50
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
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Full name of responsible person
Masoumeh Farahani
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Full name of responsible person

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Student

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
Only part of the information, such as information on the main outcome or the like, can be shared.

When the data will become available and for how long
Start the access period 6 months after publishing the results

To whom data/document is available
Data for researchers and people who are engaged in treatment can apply to them.

Under which criteria data/document could be used
Data for researchers and people who are engaged in treatment can apply to them.

From where data/document is obtainable
by Email hadis1993hashemi@gmail.com

What processes are involved for a request to access data/document
by Email hadis1993hashemi@gmail.com

Comments
6 months after publishing the results.