

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)

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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
۱۴۳۹۶۱۴۵۳۵

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 misoprostol 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

Masoumeh Farahani

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Shohada Square, Kamali St., Kamali Educational and Medical Center

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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**

Karaj University of Medical Sciences

Full name of responsible person

Masoumeh Farahani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Seyede Batool Hasanpoor-Azghady

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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آدرس خیابان No. 1996713883, Rashid Yasemi Ave., Valiance Ave., School of Nursing & Midwifery., Tehran Town,

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Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

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Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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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.