

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of induction of abortion in the first trimester using misoprostol and misoprostol with estrogen priming

Protocol summary

Summary

Objective: To determine and compare the induction of abortion in the first trimester using misoprostol and misoprostol with estrogen priming. Design: This study will be conducted in two-way fashion. The patient and person who will check the symptoms and consequences of taking the drug will be unaware of the type of drug used. The result will be expressed according to the code of each drug. Randomized randomization is blocked with 10 blocks, and patients will be assigned to the appropriate group according to the order of referral in order of assignment to each group. In the misoprostol recipient, this medication at 800 µg every 8 hours (4 pills 200 µg) will be placed vaginal in the posterior fornix. In the other group, the first dose of misoprostol, oral estrogen valerate with a dose of 2 mg to the patient. The data will continue to be similar to the previous one. Entry Criteria: Pregnant women aged 6 weeks to 14 weeks have two Missed Abortion ultrasounds. Exit criteria: history of cesarean section, renal or hepatic disease, pulmonary disease, coagulation disorders, evidence or history of thromboembolism, prostaglandin allergy, cigarette smoking, water repellent, vaginal bleeding, history of thromboembolism, intrauterine device, any amount of natural nursing tests. Blood pre-treatment (CBC, liver function tests, and liver function tests including blood urea, creatinine), uncontrolled seizure disorders. Study size: 100 patients, 50 patients in the study group and 50 controls

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070934981N1**

Registration date: **2017-07-16, 1396/04/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-16, 1396/04/25

Registrant information

Name

Maryam Esmaeilpour

Name of organization / entity

Univercity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Government , Zahedan University of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of induction of abortion in the first trimester using misoprostol and misoprostol with estrogen priming

Public title

The effect of estrogen and misoprostol on abortion

Purpose

Treatment

Inclusion/Exclusion criteria

Entry Criteria: Pregnant women aged 6 weeks to 14 weeks have two Missed Abortion ultrasounds. Exit criteria: history of cesarean section, history of adrenal, kidney or liver disease, pulmonary disease, coagulation disorders, evidence of thromboembolic events, prostaglandin sensitivity, smoking, water repellent, vaginal bleeding, history of thromboembolism, estrogen dependent cancers Breast and genital system), intrauterine device, any normal amount of blood. Pre-treatment blood tests include CBC, liver and kidney function tests including blood urea, creatinine, albumin, globulin, liver enzymes, electrolytes, severe anemia, disorders Uncontrolled seizures

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double 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 Zahedan University of Medical Sciences

Street address

University Street, Dr Hasabe Square

City

Zahedan

Postal code**Approval date**

2017-05-21, 1396/02/31

Ethics committee reference number

IR.ZAUMS.REC.1396.9

Health conditions studied**1****Description of health condition studied**

Abortion

ICD-10 code

O02.1

ICD-10 code description

Early fetal death with retention of dead fetus

Primary outcomes**1****Description**

Successful abortion

Timepoint

4 hours after disposal of pregnancy

Method of measurement

Based on the amount of pregnancy residues in ultrasound after excretion of pregnancy products

Secondary outcomes**1****Description**

Misoprostol side effects

Timepoint

Immediately after starting treatment

Method of measurement

Based on completed patient questionnaire

Intervention groups**1****Description**

In this study, the aim of this study was to examine the induction of abortion in the first trimester using misoprostol and misoprostol with estrogen priming, randomly divided into two groups receiving misoprostol and misoprostol with estrogen priming. In the misoprostol-containing group, this medication at 800 µg every 8 hours (4 pills 200 µg) will be placed vaginal in the posterior foreskin (up to a maximum dose of 2400 µg), followed by side effects of fever, sweating, fatigue, Nausea, vomiting, abdominal pain ... and the time taken to remove tissue and will be recorded in the patient's case. Four hours after the removal of the tissue, ultrasound is performed for the patient and if the pregnancy remains below 10 mm, the abortion is considered successful and if the remains are more than 10 mm, the curettage will be performed for the patient. In the misoprostol group with estrogen priming, we will also work on the misoprostol group, with the exception that in this group, the first dosage of misoprostol will be given to the patient with oral estrogen valerima with a dose of 2 mg and the study will continue to be similar to that of the previous group. were.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali ebn Abi Taleb Hospital, Zahedan

Full name of responsible person

Maryam Esmaeilpour

Street address

Ali ebn Abi Taleb Hospital, Khalij Fars Bolvard

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Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zahedan University of Medical Sciences

Full name of responsible person

Maryam Esmeilpour

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University Street. Dr Hasabi's Square

City

zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Maryam Esmaeilpour

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Assistant of Obstetrics and Gynecology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty