# 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 forronix. 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
**City**
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
**Street address**
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**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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*