Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of misoprostol with letrozole and without letrozole to induce abortion in the second trimester of pregnancy

Protocol summary

Summary

This study will be done with aime to investigate the effect of misoprostol with letrozole to induction abortion in the second trimester of pregnancy. This study is a double-blind clinical trial. The study population will be pregnant women who refer to Imam Reza hospital in Kermanshah city with gestational age of 13 -23 week's, which has indicated termination of pregnancy in drug method and 120 persons will selected and randomly will assigned to two experimental and control groups. In the experimental group letrozole tablets orally at a dose of 2 .5 mg in the form of two tablets given every 12 hours for two days.The beginning of the third day Misoprostol tablets at a dose of 100 mg as 4 tablets every 6 hours, up to 3 doses means 1200 micrograms given vaginally. The control group will receive 8 placebo tablets on two consecutive days, 2 tablets every 12 hours given. Then from the third day, vaginal misoprostol of 100 micrograms as a 4 tablets with a maximum of 3 doses will given every 6 hours. Blood pressure, heart rate and body temperature measured every 2 hours. Fever, nausea, diarrhea, abdominal pain, bleeding and tissue rejection time will also be recorded. Then the time interval between discharge pregnancy products from the first prescribed dose of misoprostol will be recorded for each patient. Patient initial hemoglobin and post-abortion hemoglobin will be measured. In this study for all patients curettage is performed in the operating room routinely and patients' hemoglobin control also will be 6 hours after curettage. Inclusion criteria: gestational age of 13 to 22 with an indication for termination of pregnancy in medical method; Chorioamionitic. Exclusion criteria: patients with a history of caesarean section; Maternal serious chronic systemic and chronic disease.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015123114333N48**
Registration date: **2016-03-02, 1394/12/12**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-03-02, 1394/12/12

Registrant information

Name
Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

Expected recruitment start date

2016-01-25, 1394/11/05

Expected recruitment end date

2017-07-27, 1396/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of misoprostol with letrozole and without letrozole to induce abortion in the second trimester of

pregnancy

Public title
Comparison investigation of the effect of Letrozole misoprostol to induce abortion in the second trimester of pregnancy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Gestational age of 13 to 22 with an indication for termination of pregnancy in medical method; Chorioamionitic. Exclusion criteria: Patients with a history of caesarean section; Maternal serious chronic systemic and chronic disease; Cardiovascular disease.
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Randomly by tossing coin

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kermanshah University of Medical Sciences
Street address
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
City
Kermanshah
Postal code
Approval date
2015-01-16, 1393/10/26
Ethics committee reference number
45253/7/420/پ

Health conditions studied

1

Description of health condition studied
Termination of pregnancy in the second trimester
ICD-10 code
O04
ICD-10 code description
Medical abortion

Primary outcomes

1

Description
Duration of induction to abortion
Timepoint
From admission until 48 hours later
Method of measurement
Doctor observation

2

Description
Blood pressure
Timepoint
Baseline, every 2 hours, discharge time
Method of measurement
Manometer

3

Description
Heart rate
Timepoint
Baseline, every 2 hours, discharge time
Method of measurement
By doctor

4

Description
Temperature
Timepoint
Baseline, every 2 hours, discharge time
Method of measurement
By thermometer

Secondary outcomes

empty

Intervention groups

1

Description
In the experimental group letrozole tablets orally at a dose of 2 .5 mg in the form of two tablets given every 12 hours for two days. At the beginning of the third day Misoprostol tablets at a dose of 100 mg as 4 tablets

every 6 hours, up to 3 doses means 1200 micrograms given vaginally.

Category

Treatment - Drugs

2

Description

The control group will receive 8 placebo tablets on two consecutive days , 2 tablets every 12 hours given. Then on the third day, vaginal misoprostol of 100 micrograms as a 4 tablets every 6 hours with a maximum of 3 doses will given

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Negin hajiali Akbari

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences

Full name of responsible person

Koroush Hamzehee

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

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, Kermanshah 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Anisodole Nankali

Position

Obstetricians

Other areas of specialty/work

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Emam Reza Hospital, Parastar Boulevard

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Web page address

Person responsible for updating data

Contact

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