Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of vaginal misoprostol, combination of vaginal misoprostol and letrozole and combination of misoprostol and laminaria for preoperative cervical ripening in under second trimester abortions

Protocol summary

Summary

Objectives: Comparison of the efficacy of vaginal misoprostol with and without letrozole and combination of misoprostol and laminaria for preoperative cervical ripening among women with under second trimester abortion. Design: In this interventional study, 120 pregnant women under 20 weeks of gestational age who are candidates for therapeutic abortion will be selected and divided into three groups using block randomization method (n=40 in each group). Inclusion criteria: Under 20 weeks pregnancy and fetal death. Exclusion criteria: Cesarean section history; adrenal diseases; asthma; history of thromboembolism. Proper counseling will be done and a written informed consent will be obtained before starting the treatment regimen. Setting and conduct: One group will receive vaginal misoprostol alone (produced by Pfizer Company), 600 µg every 4 hours for 5 days for women in the gestational age of 13 weeks or less and 200 µg every 4 hours for 5 days in women with the gestational age of 14 - 20 weeks and the second group will receive oral placebo and vaginal misoprostol (like the first group), also they will receive 5 mm laminaria (produced by Cytotec Company) for 6 hours as well. In the third group, oral letrozole (Iran Hormon Company), 10 mg daily in combination with cervical placebo will be prescribed on first and second day and in third day, patients will be hospitalized and receive vaginal misoprostol (like the first group) and third dose of oral letrozole. Patients will regularly be examined every 4 hours and in the absence of abortion, vaginal misoprostol will be repeated after 4 hours. Eight hours after intervention, patients will be assessed using transvaginal ultrasound and no report of products of conception (POC) will be considered as complete abortion and the patient will be discharged. Otherwise, patients will be assessed by transvaginal ultrasound again on next day. For patients who have uncompleted expulsion of POC, curettage abortion will be done. For every patient, pain intensity on the VAS scale will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100923559N6**
Registration date: **2016-12-30, 1395/10/10**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-12-30, 1395/10/10

Registrant information

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Name of organization / entity
Ardabil University of Medicine Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ardabil University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-04-21, 1396/02/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of vaginal misoprostol, combination of vaginal misoprostol and letrozole and combination of misoprostol and laminaria for preoperative cervical ripening in under second trimester abortions

Public title
Use of vaginal misoprostol with and without letrozole and combination of misoprostol and laminaria for preoperative cervical ripening
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Under 20 weeks pregnancy and fetal death. Exclusion criteria: Cesarean section history; adrenal diseases; asthma; history of thromboembolism
Age
No age limit
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ardabil University of Medical Sciences
Street address
Ardabil University of Medicine Sciences, Daneshgah street, Ardabil
City
Ardabil
Postal code
53141-56198
Approval date
2016-10-30, 1395/08/09
Ethics committee reference number
IR.ARUMS.REC.1395.55

Health conditions studied

1

Description of health condition studied
Medical abortion
ICD-10 code
000-008
ICD-10 code description
Medical abortion

Primary outcomes

1

Description
Fetus abortion
Timepoint
Eight hours after the intervention, and every twenty-four hours up to three days if the abortion doesn't occur
Method of measurement
Transvaginal Ultrasonography

Secondary outcomes

1

Description
Pain
Timepoint
Every four hours until abortion occurs and at the time that abortion occurs
Method of measurement
Visual analog scale

Intervention groups

1

Description
Intervention group 1: Vaginal misoprostol, produced by Pfizer Company, 600 µg every 4 hours for 5 days in women with the gestational age of 13 weeks or less and 200 µg every 4 hours for 5 days in women with the gestational age of 14 -20 weeks
Category
Treatment - Drugs

2

Description
Intervention group 2: Oral letrozole, produced by Iran Hormon Company, 10 mg daily and vaginal misoprostol, produced by Pfizer Company, 600 µg every 4 hours for 5

days for women in the gestational age of 13 weeks or less and 200 µg every 4 hours for 5 days in women with the gestational age of 14 - 20 weeks.

Category

Treatment - Drugs

3

Description

Intervention group 3: vaginal laminaria, produced by Cytotec Company, 5mm for 6 hours and vaginal misoprostol, produced by Pfizer Company, 600 µg every 4 hours for 5 days for women in the gestational age of 13 weeks or less and 200 µg every 4 hours for 5 days in women with the gestational age of 14 - 20 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi Hospital

Full name of responsible person

Dr. Mahsa Valaee

Street address

Alavi Hospital, Moadi street, Ardabil

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ardabil University of Medical Sciences

Full name of responsible person

Dr Shahram Habibzadeh

Street address

Ardabil University of Medical Science, Daneshgah street, Ardabil, Iran

City

Ardabil

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, Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Dr. Mahsa Valaee

Position

Gynecology Asisstant

Other areas of specialty/work

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Full name of responsible person

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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