Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effect of misoprostol and letrozole in the first-trimester abortion of patients referring to Ganjavian Hospital in Dezful in 1400

Protocol summary

Study aim

A comparative study of the therapeutic effects of two different letrozole and misoprostol regimens in the first-trimester abortion

Design

single-blind

Settings and conduct

Proper counseling will be done and written informed consent will be obtained before starting the treatment regimen. Group A patients will receive 2 misoprostol tablets orally and two vaginally in the posterior fornix of the vagina (800µg) and this dose will be repeated up to 3 times every 4 hours as needed. In groups B and c, 10 mg of oral letrozole (2.5 mg) was administered twice daily for 3 and 5 days, respectively, on the last day of letrozole administration, patients will be hospitalized and receive vaginal misoprostol 400 µg of misoprostol vaginally , 400 µg of misoprostol will be used sublingually in both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: hemoglobin level more than 10 gr/liter , diastolic pressure less than 95 mm Hg, gestational age less than 14 weeks Exclusion criteria: use of drugs in the last three months for abortion, pregnancy pruritis , adrenal disorders, porphyria, steroid-dependent cancer, acute or chronic liver disease ، thromboembolism, history of chronic lung diseases ، known allergy to letrozole or misoprostol, lactation, multifetal pregnancy, more than two previous cesarean sections, history of uterine surgery and myomectomy, contraindications to misoprostol and letrozole, intrauterine devices, uncontrolled seizures, coagulation disorder or use Anticoagulants, Active liver disease, Cardiovascular disease, Glucocorticoid use

Intervention groups

In this interventional study, 75 pregnant women under 14 weeks of gestational age who are candidates for therapeutic abortion will be selected and divided into three groups using the block randomization method (n=25 in each group).

Main outcome variables

Medical abortion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200217046521N1**
Registration date: **2021-10-03, 1400/07/11**
Registration timing: **registered_while_recruiting**

Last update: **2021-10-03, 1400/07/11**
Update count: **0**

Registration date

2021-10-03, 1400/07/11

Registrant information

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Vahid Kheirandish
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 61 4223 0453
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-21, 1400/06/30

Expected recruitment end date

2023-03-21, 1402/01/01

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

Scientific title
Comparison of the effect of misoprostol and letrozole in the first-trimester abortion of patients referring to Ganjavian Hospital in Dezful in 1400

Public title
Evaluation of the effects of misoprostol and letrozole in therapeutic abortion
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Hemoglobin level greater than 10 gr / l Diastolic pressure less than 95 mmhg Serum hcg level less than 3000 iu / l Gestational age less than 14 weeks
Exclusion criteria:
Use of abortion drugs in the last three months itching during pregnancy Existence of adrenal disorders Porphyria, steroid-related cancer, acute or chronic liver disease or thromboembolism History of chronic lung diseases such as asthma, bronchitis, bronchiectasis known allergy to letrozole or misoprostol Breast feeding Multipfetal pregnancy More than two previous cesarean sections uterine surgery and myomectomy contraindications to the letrozol and mosoprostol Existence of intrauterine devices (IUD) Uncontrolled seizures Coagulation disorder or use of anticoagulants Active liver disease, cardiovascular disease Adrenal disease Consumption of glucocorticoids
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize the samples and also to balance the study groups, patients will be divided into 3 groups by the block randomization method by the researcher. In this method, the researcher will place each patient in one of 3 groups: A (misoprostol) or B (3-day letrozole + misoprostol) or C (5-day letrozole + misoprostol). Blocking in the form of six blocks One will be done and 8 blocks will be formed according to the number of sample population. We predict all possible arrangements of groups, for example, the first block will be AABBCC and the next block. For example, it will be predicted as CAB CAB and the rest of the blocks will be defined in the same way. Due to the large number of blocks, block randomization software will be used and then 8 blocks will be selected randomly with the help of a table of random numbers. Individuals will also be randomly selected and placed in blocks. Eventually, the sample size will be the same in the groups and 25 patients will be in each group A, B and C.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants in the study will be placed in three ABC groups by the researcher. Patient randomization will be done by the researcher in blocks and after coding, the study and control groups will enter the data for analysis in the software The group treated with misoprostol with code A, the group treated with letrozole 3 days + misoprostol with code B and the group treated with letrozole 5 days + misoprostol with code C will be coded. It should be noted that the participants in the study do not know about the treatment and medication regimen performed for them, but researchers and statistical analysts know what diet each participant received.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committees of Dezful University of Medical Sciences
Street address
Azadegan Boulevard, Daneshjoo Square
City
Dezful
Province
Khouzestan
Postal code
6461665145
Approval date
2020-10-31, 1399/08/10
Ethics committee reference number
IR.DUMS.REC.1399.047

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

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Group A patients in whom abortion will be performed with vaginal and oral misoprostol are given two 200 µg misoprostol tablets orally (sublingually) and two vaginally in the posterior vaginal fornix (800µ totally) and then this amount will be repeated every 4 hours p to 3 days as needed.Intervention group: In group B, where abortion is performed vaginally with oral letrozole and misoprostol, 10 mg of oral letrozole is given to the patient twice daily for 3 days (2 tablets of 2.5 mg each) followed by 400 mg. Misoprostol will be used vaginally in the posterior fornix and 4g400 misoprostol will be used sublingually.
Category
Treatment - Drugs

2

Description
Intervention group: In group B, abortion treatment with oral letrozole and misoprostol will be performed vaginally, 10 mg oral letrozole for 3 days for the patient in two meals a day (2 tablets of 2.5 mg each meal) is prescribed on an outpatient basis and then in On the last day of taking letrozole, 400 mg of misoprostol will be administered vaginally in the posterior fornix and 400 mg of misoprostol will be used sublingually.
Category
Treatment - Drugs

3

Description
Intervention group: In group B, abortion treatment with oral letrozole and misoprostol will be performed vaginally, 10 mg oral letrozole for 5 days for the patient in two meals a day (2 tablets of 2.5 mg each meal) is prescribed on an outpatient basis and then in On the last day of taking letrozole, 400 mg of misoprostol will be administered vaginally in the posterior fornix and 400 mg of misoprostol will be used sublingually.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ganjavian Hospital, Dezful
Full name of responsible person
Sima Janati
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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
Dezfoul University of Medical Sciences
Proportion provided by this source
100
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
Dezfoul University of Medical Sciences
Full name of responsible person
vahid.kheirandish
Position
Non-faculty, anesthesiologist
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Bachelor
Other areas of specialty/work
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Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not 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
All documents and statistical tests and the results will be mentioned in the form of graphs and tables in the final article
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
By publishing the article, all people who have access to the Internet can access the results
Under which criteria data/document could be used
In order to develop the science related to abortion treatment and facilitate the process with the least complications, everyone will be able to access
From where data/document is obtainable
It will be available on Google Scholar by mentioning the names of the authors and keywords

What processes are involved for a request to access data/document	nothing
	Comments