Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of letrozole with misoprostol on induced abortion in the second trimester

Protocol summary

Study aim

The effect of letrozole with misoprostol on induced abortion in the second trimester

Design

Study Design : Randomized ; Target population: Pregnant women with under 13 weeks nonviable pregnancy. Inclusion criteria : pregnancy with under 13 weeks nonviable fetus .Exclusion criteria : any condition requiring emergency intervention .76 participants were randomized into two groups.control group use Misoprostol for abortion and intervention group will receive Letrozole plus Misoprostol .

Settings and conduct

76 consecutive pregnant women with gestational age of 13-26 weeks who were candidate for stopping pregnancy due to fetal reasons who come to Tabriz,Alzahra hospital.76 participants were randomized into two groups. Control group use Misoprostol for abortion (gold standard treatment) and intervention group will receive Letrozole plus Misoprostol .

Participants/Inclusion and exclusion criteria

Inclusion criteria: Gestational age of 13 to 26 with an indication for termination of pregnancy in medical method; Reason for termination of pregnancy, such as missed abortion; Pregnancy NULL; Therapeutic abortion legal authorization and consent of patients Exclusion criteria:Pain and bleeding; Drug sensitivity to misoprostol; history of corticosteroid use

Intervention groups

Intervention group: 7.5 mg ، letrozole (Manufacturing Iran Hormones Company) prescribed up to three doses at home, the patient was hospitalized on the fourth and Misoprostol 400 micrograms (made by SEARLE UK) is administered sublingually every 3 hours to a maximum of 5 doses. Control group: The group received placebo for 4 days (Folic acid as blind-made by IRAN DARO) and then misoprostol according to the ACOG protocol.

Main outcome variables

Primary out come is rate of complete abortion and Secondary outcomes are rate and duration of bleeding and other side effects such as nausea , vomiting , diarrhea , dizziness , headache.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130626013777N2**
Registration date: **2019-02-14, 1397/11/25**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-14, 1397/11/25**
Update count: **0**

Registration date

2019-02-14, 1397/11/25

Registrant information

Name
Shamsi Abbasalizadeh
Name of organization / entity
Tabriz University of Medical Sciences
Country
Iran (Islamic Republic of)
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+98 41 1553 9161
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-13, 1397/11/24

Expected recruitment end date

2020-02-13, 1398/11/24

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of letrozole with misoprostol on induced abortion in the second trimester

Public title
Comparison the effect of Letrozole with Misoprostol on induction of second trimester abortion in pregnancy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
patients more than 18 years of age Gestational age of 13 to 26 with an indication for termination of pregnancy in medical method Hb above 10 Reason for termination of pregnancy, such as missed abortion; Pregnancy NULL; Therapeutic abortion legal authorization and consent of patients BMI between 25-25
Exclusion criteria:
Pain and bleeding Drug sensitivity to misoprostol; Severe anemia Coagulopathy or taking anticoagulants Active liver disease Cardiovascular disease and uncontrolled seizures Adrenal disease history of corticosteroid use
Age
From **18 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were randomly assigned to two groups of 38 A (receiving Letrozole and Misoprostol) and B (Misoprostol) by using the random numbers table.
Blinding (investigator's opinion)
Not 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 Tabriz University Of Medical Sciences
Street address
Third Floor, Central Building of Number2, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166616471
Approval date
2019-01-21, 1397/11/01
Ethics committee reference number
IR.TBZMED.REC.1397.855

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
abortion
Timepoint
The start of the intervention up to 24
Method of measurement
Ultrasound

2

Description
Time between medication abortion
Timepoint
The start of the intervention up to 24
Method of measurement
hour

3

Description
The need for curettage
Timepoint
Seven days after abortion
Method of measurement
Clinical

Secondary outcomes

1

Description
Side effects

Timepoint
Intervention to 24 hours after administration
Method of measurement
Clinical

Intervention groups

1

Description
Intervention group: 7.5 mg ، letrozole (Manufacturing Iran Hormones Company) prescribed up to three doses at home, the patient was hospitalized on the fourth and Misoprostol 400 micrograms (made by SEARLE UK) is administered sublingually every 3 hours to a maximum of 5 doses.
Category
Treatment - Drugs

2

Description
Control group: The group received placebo for 4 days (Folic acid as blind-made by IRAN DARO) and then misoprostol according to the ACOG protocol.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Shamsi Abbasalizadeh
Street address
Alzahra Hospital, South Artesh St.
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Tabriz
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5138665793
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
معاونت تحقیقات و فناوری دانشگاه علوم پزشکی تبریز
Full name of responsible person
Abolghasem Juiban
Street address
Third Floor, Central Building of Number2, Golgasht Street
City
Tabriz
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Postal code
5138665793
Phone
+98 41 3553 9161
Email
lahroudin@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
معاونت تحقیقات و فناوری دانشگاه علوم پزشکی تبریز
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
Tabriz University of Medical Sciences
Full name of responsible person
Shamsi Abbasalizadeh
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available