Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparison the effect of Letrozole plus Misoprostol and Misoprostol alone in termination of nonviable first trimester pregnancies; A single Blinded Randomized Trial.

Protocol summary

Summary

This study wants to comparing letrozole plus misoprostol with misoprostol alone in termination of nonviable pregnancy in the first trimester . Study Design : Randomized , Single-blind , Two- center , Controlled with standard treatment without placebo. Target population: Pregnant women with under 12 weeks nonviable pregnancy. Inclusion criteria : pregnancy with under 12 weeks nonviable fetus without any other systemic or emergency problems . Main exclusion criteria : any condition requiring emergency intervention . Sample size: 124 participants were randomized into two groups. In this study , control group use Misoprostol for abortion (gold standard treatment) and intervention group will receive Letrozole plus Misoprostol . in Intervention group, 3 days after treatment will check the serum level of Estradiol then both groups will receive Misoprostol tablets 600 mg orally as a single dose. Patients will be monitored for 4 hours after taking Misoprostol to the complications like bleeding and abdominal pain , then will discharge. The next visit will take about 15 days later and Ultrasonography for ِRetained Products of Conception and check the hemoglobin level. If abortion not happen,then curettage will take place. Patients based on the evaluation results (abortion happen or not) will be divided in two groups (response and non-response) to treatment. 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 , pain in the lower part of the abdomen , fever and chills and differences in serum level of estradiol before and after treatment with Letrozole .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030114293N1**
Registration date: **2014-03-14, 1392/12/23**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-03-14, 1392/12/23

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source
Tabriz University of Medical Sciencies

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Letrozole plus Misoprostol and Misoprostol alone in termination of nonviable first trimester pregnancies; A single Blinded Randomized Trial.

Public title
Comparison the effect of Letrozole plus Misoprostol and Misoprostol alone in termination of nonviable first trimester pregnancies
Purpose
Treatment
Inclusion/Exclusion criteria
Main inclusion criteria: over age 18 pregnant women with nonviable pregnancy under 12 weeks on the first day of the last menstrual without other systemic problems.
Main exclusion criteria: acute illness that requires any urgent intervention and treatment.
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **124**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tabriz University of Medical Sciences
Street address
Golgasht st, tabriz
City
Tbriz
Postal code
Approval date
2014-03-03, 1392/12/12
Ethics committee reference number
92222

Health conditions studied

1

Description of health condition studied
Therapeutic Abortion
ICD-10 code
O04.4 - O0
ICD-10 code description
Medical abortion : incomplete, without complication

Primary outcomes

1

Description
Abortion Rate
Timepoint
Two weeks after intervention
Method of measurement
Ultrasonography

Secondary outcomes

1

Description
Gastrointestinal problems
Timepoint
From intervention to abortion time.
Method of measurement
Clinical exam

2

Description
Decrease in hemoglobin
Timepoint
Just before intervention and two weeks later.
Method of measurement
Laboratory

Intervention groups

1

Description
Intervention group: 10 mg (4 tablets 2.5 mg) letrozole for 3 days and after 3 days, 600 mcg (3 tablets of 200 mcg) of misoprostol as single dose.
Category
Treatment - Drugs

2

Description
Control group: 600 mcg (3 tablets 200 mcg) as a single dose.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra hospital
Full name of responsible person
Paria Sadeghi Shabestari
Street address
South Artesh st, Tabriz
City
Tabriz

2

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Paria Sadeghi Shabestari
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Rah Ahan sq, Tabriz
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Women's Reproductive Health Research Center
Full name of responsible person
Dr.Elaheh Madarek
Street address
Al-Zahra hospital, South Artesh, Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Women's Reproductive Health Research Center
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
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Web page address

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