

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

Name

Fatemeh Abbasalizadeh

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Phone

+98 41 1553 9161

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

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

Street address

Rah Ahan sq, Tabriz

City

Tabriz

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

Tabriz university of medical sciences\ Al-Zahra hospital

Full name of responsible person

Paria Sadeghi Shabestari

Position

resident of gynecology

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Position

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Other areas of specialty/work**Street address**

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Fax**Email**

psmed382@yahoo.com

Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty