

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The compression of Misoprostol effect with and without Letrozole in first trimester abortion: A randomized clinical trial study

Protocol summary

Summary

The aim of current study is to examine the effect of Misoprostol with and without Letrozole in first trimester abortion. In this study 110 pregnant women are selected who are in the first trimester and attend at Rouhani hospital for termination of pregnancy. They are selected according to Inclusion criteria (NULL Pregnancy and etc.) and Exclusion criteria (sever bleeding and etc.) and randomly placed in two groups. In the Intervention group, treatment is performed on an out-patient basis for 2 days with oral Letrozole (made by Iran Hormone Co.), 7.5 mg daily, followed by 800 mcg vaginal Misoprostol (made by SEARLE Co.) on the third day of treatment that is placed in the posterior Fornix. In the control group treatment is performed by placebo (Folic acid as single blind - made by Iran Daru Co.) for 2 days and on the third day 800 mcg vaginal Misoprostol is placed in the posterior Fornix. To use of Misoprostol, each patient is admitted and both of the groups are monitored for 24 hours and then checked by sonography. Excretion of pregnancy products after 7 days is a sign of success in this method. If excretion after 7 days does not happen, it is a sign of failure in this method, and other methods like curettage are used. In current study primary outcomes are considered as complete abortion, time between medication and abortion and need for curettage. Secondary outcomes are drug adverse effects including fever, severe bleeding, diarrhea, Vomiting and skin rash.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201412111760N37**

Registration date: **2014-12-22, 1393/10/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-22, 1393/10/01

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3236 2282

Email address

zahra@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Research and Technology, Babol University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

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

The compression of Misoprostol effect with and without Letrozole in first trimester abortion: A randomized clinical trial study

Public title

The compression of Misoprostol effect with and without

Letrozole in first trimester abortion: A randomized clinical trial study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Following 12 weeks of pregnancy; 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; Severe anemia; Coagulopathy or taking anticoagulants; Active liver disease; Cardiovascular disease and uncontrolled seizures; Adrenal disease, or a history of corticosteroid use

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Babol University of Medical sciences

Street address

Babol University of Medical Sciences, Gangafroz Avenue

City

Babol

Postal code

Approval date

2014-01-14, 1392/10/24

Ethics committee reference number

3609

Health conditions studied

1

Description of health condition studied

Termination of pregnancy in the first trimester

ICD-10 code

P96.4

ICD-10 code description

Termination of pregnancy, fetus and newborn

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

Ultrasound

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: In the Intervention group treatment is being performed on an out-patient basis for 2 days with Letrozole (made by Iran Hormone Co.) as 7.5 mg orally once a day, and on the third day 800 mcg vaginal Misoprostol (made by SEARLE Co.) is being placed in the posterior Fornix.

Category

Treatment - Drugs

2

Description

Control Group: In the control group treatment is being performed by placebo (folic acid as single blind – made by Iran Daru Co.) for 2 days and on the third day 800 mcg vaginal Misoprostol is being placed in the posterior Fornix.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Zeinab Azmoodeh Fard

Street address

Ayatollah Rouhani Hospital, Gangafroz Avenue

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Babol University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

Street address

Babol University of Medical Sciences, Ganjafroz Avenue

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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

Vice Chancellor for Research and Technology, Babol 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

Babol University of Medical Sciences

Full name of responsible person

Dr. Zeinab Azmoodeh Fard

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Gynecologist

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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