

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Vaginal versus oral Misoprostol for second-trimester pregnancy termination

Protocol summary

Summary

Termination of second trimester of pregnancy is carried out with medical and surgical methods. In these methods, misoprostol is noticed due to cheap cost and stability at room temperature. The aim of this study is comparing vaginal versus oral misoprostol for second-trimester pregnancy termination. In this study 40 women with inclusion criteria (14-24 weeks of gestation singleton) that their pregnancy should be terminated due to maternal or fetal cause and exclusion criteria (Multiple pregnancy, Chorioamnionitis, previous uterus incision, parity over 3, patients with asthma, liver, kidney and heart disease) enter to study. The patients will be randomized in two groups, and they will be matched using maternal age and parity. At first, all of patients receive 600 µg vaginal Misoprostol and then they will be randomized to receive either oral or vaginal misoprostol 400 mg every 4 hours for a maximum of 3 doses. Finally, efficacy of treatment (rate of termination) and complication (severe vaginal bleeding, fever and curettage) will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103281760N11**

Registration date: **2011-11-01, 1390/08/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-11-01, 1390/08/10

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

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

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2010-03-16, 1388/12/25

Expected recruitment end date

2011-09-21, 1390/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Vaginal versus oral Misoprostol for second-trimester pregnancy termination

Public title

Vaginal versus oral Misoprostol for second-trimester pregnancy termination

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women Hospitalized in the second-trimester (24-14 weeks gestation) for abortion with single pregnancy, parity conditions 1 to 3, without pain, uterine infection and dilatation are less than 2cm.

Exclusion criteria: Multiple pregnancy, Chorioamnionitis previous uterus incision, parity over 3, patients with asthma, liver, kidney and heart disease.

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Ethics committee of Babol University of Medical sciences

Street address

Babol University of Medical Sciences, Gangafroz Avenue

City

Babol

Postal code

Approval date

2010-04-20, 1389/01/31

Ethics committee reference number

30/165/پ/ز

Health conditions studied

1

Description of health condition studied

Second trimester termination of pregnancy

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 hours

Method of measurement

Clinical examinations

Secondary outcomes

1

Description

Number of tablets consumed

Timepoint

The start of the intervention up to 24 hours

Method of measurement

Clinical examinations

2

Description

Possible Complications

Timepoint

The start of the intervention up to 24 hours

Method of measurement

Clinical examinations

3

Description

Amount of bleeding

Timepoint

The start of the intervention up to 24 hours

Method of measurement

Clinical examinations

4

Description

The need for curettage

Timepoint

The start of the intervention up to 24 hours

Method of measurement

Clinical examinations

Intervention groups

1

Description

First group: 600 µcg vaginal Misoprostol as initial dose, and then 400 micrograms of oral misoprostol every four hours up to receive three doses.

Category

Treatment - Drugs

2

Description

Second group: 600 µcg vaginal Misoprostol as initial dose, and then 400 micrograms of vaginal misoprostol every four hours up to receive three doses.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Masoumeh Enayati

Street address

Ayatollah Rouhani Hospital, Gangafroz Avenue

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology

Full name of responsible person

Dr. Ali Bijani

Street address

Babol University of Medical Sciences, Gangafroz 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

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

Fatemehzahra Fertility & reproductive Health Research Center

Full name of responsible person

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Position

M.A/Responsible for Public Affairs Research Center

Other areas of specialty/work

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Person responsible for scientific inquiries

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Department of Obstetrics and Gynecology, Ayatollah Rouhani Educational Center

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Gynecologist

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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