

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of vaginal and sub-lingual misoprestol for induction of therapeutic abortion at 12- 20 weeks gestational age 2012-13

Protocol summary

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Summary

Background: To identify an effective misoprostol for the termination of 12-20 week of pregnancy, we compared sublingual and administration of multiple doses of misoprostol in a randomized, placebo-controlled methods: 480 pregnant women requesting medical abortion at 12-20week into two treatment groups: 400 mg of misoprostol administered either sublingually or vaginally every 6 h, followed by sublingual administration of 400 mg misoprostol every 6. Successful abortion within 48 h was also considered as an outcome along with the inductionto-abortion-interval, side effects and women's satisfactionon these treatments.

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-04-01, 1391/01/13

Expected recruitment end date

2013-04-01, 1392/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2013040912958N1**

Registration date: **2013-06-17, 1392/03/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-06-17, 1392/03/27

Registrant information

Name

Yassaman Aghajani

Name of organization / entity

Tehran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2373

Email address

Scientific title

Comparison of vaginal and sub-lingual misoprestol for induction of therapeutic abortion at 12- 20 weeks gestational age 2012-13

Public title

Misoprostol in therapeutic abortion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : All pregnant women with gestational age between 12 and 20 weeks who have medical indications for pregnancy termination 20-40 years old including fetal indications like structural or chromosomal fetal abnormalities, PROM, intrauterine fetal death or maternal indication such as pregnant women with hemoglobin less than 10 mg. Exclusion Criteria: pregnant women with any type of allergic reaction to misoprestol, pregnant women high risk for rupture of uterine, history of classic uterine incision or T-shaped incision, women with a history of extensive surgery on the fundus of the uterus, pregnant women with IUD, women with certain medical conditions such as severe anemia, clotting disorders or taking anticoagulant medication, active liver

disease, glaucoma, uncontrolled seizure disorders, adrenal disease or disorder that requires treatment with glucocorticoids such as tracheobronchial asthma, Smoking more than 20 cigarettes per day, gynecologic abnormalities confirmed by ultrasound, mitral stenosis, sickle cell anemia, diastolic blood pressure more than 90 mm Hg, systolic pressure less than 90 mmHg, history of thromboembolism and liver disease, hemolytic disorders and a history of two cesareans.

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **480**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not 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, Faculty of Medicine

Street address

Faculty of Medicine, Tehran University of Medical Sciences and Health Care

City

Tehran

Postal code

-

Approval date

2012-05-26, 1391/03/06

Ethics committee reference number

91/176/130/s

Health conditions studied**1****Description of health condition studied**

Therapeutic abortion

ICD-10 code

O04

ICD-10 code description

Therapeutic Abortion

Primary outcomes**1****Description**

complete evacuation of products of conception

Timepoint

24-48 h

Method of measurement

Questinaire

Secondary outcomes**1****Description**

pulse rate

Timepoint

24 and 48 hr

Method of measurement

examination

2**Description**

Blood pressure

Timepoint

24 and 48 hr

Method of measurement

examination

3**Description**

uterine contraction

Timepoint

24 and 48 hr

Method of measurement

examination

4**Description**

mean induction to delivery time

Timepoint

24 and 48 hr

Method of measurement

Questionaire

5**Description**

occurrence of side effects

Timepoint

24 and 48 hr

Method of measurement

Questionaire

Intervention groups

1

Description

In group A, patients received 400 mg of sub-lingual misoprestol every 6 hours to induce abortion and administration was discontinued in cases of severe contraction.

Category

Treatment - Drugs

2

Description

Group B, received 400 mg of vaginal tablet of misoprestol, placing in the vagina every 6 hours and treatment carried on until delivery of fetus or induction of severe contractures.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr.Ali Shariati hospital

Full name of responsible person

Nazila Mesbah

Street address

Dr.Ali Shariati Hospital, North Karegar St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Shahin Akhoundzade

Street address

Tehran University of Medical Sciences

City

Tehran

Grant name

-

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Nazila Mesbah

Position

Resident of gynecology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nazila Mesbah

Position

Resident of gyencology

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nazila Mesbah

Position

Resident of gynecology

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

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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