Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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.

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

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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

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/د

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
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Person responsible for updating data

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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