Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of oral versus vaginal misoprostol for legal abortion in pregnant women: A double blind randomized clinical study

Protocol summary

Summary

The purpose of this study was to compare oral and vaginal misoprostol in pregnant women who referred to Besat Hospital of Sanandaj in 1393 for legal abortion. Total of 70 pregnant women that with Legal Medicine permission were referred to Besat Hospital of Sanandaj in order to pregnancy termination were selected. Inclusion criteria included pregnant women who were candidates of pregnancy termination with the permission of legal Medicine and exclusion criteria were pregnant women who were breastfeeding, women with severe liver disease, chronic pulmonary disease, Mitral valve stenosis, history of allergy to prostaglandins, inflammatory disease of intestines, asthma, glaucoma, hypertension, and severe bleeding. After obtaining written informed consent they were randomly divided into 2 oral misoprostol and vaginal misoprostol groups using 2 block method and table of random numbers. In oral group 200 micrograms of misoprostol was used every 6 hours up to 6 times up to 36 hours and also in vaginal group 200 micrograms of misoprostol was used every 6 hours up to 6 times up to 36 hours. To double blind the study placebo was used. In oral group, vaginal placebo and in vaginal group oral placebo was used simultaneously. Researcher and the participants in the study were not aware of the drug or placebo. At the end of the study, the efficacy of treatment method namely the rate of pregnancy products excretion and complications (bleeding, fever,uterus perforation) were measured in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014110812789N9**
Registration date: **2014-12-13, 1393/09/22**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2014-12-13, 1393/09/22

Registrant information

Name
Masoud Rasolabady
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kurdistan University of Medical Sciences

Expected recruitment start date

2014-04-04, 1393/01/15

Expected recruitment end date

2014-11-06, 1393/08/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral versus vaginal misoprostol for legal abortion in pregnant women: A double blind randomized clinical study

Public title

Comparison of oral versus vaginal misoprostol for legal abortion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: pregnant women who are candidates of pregnancy termination with the permission of legal Medicine. Exclusion criteria : pregnant women who are breastfeeding, women with severe liver disease, chronic pulmonary disease, Mitral valve stenosis, history of allergy to prostaglandins, inflammatory disease of intestines, asthma, glaucoma, hypertension, and severe bleeding.

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Sciences, Pasdaran St., Sanandaj, Iran

City

Sanandaj

Postal code

Approval date

2014-09-29, 1393/07/07

Ethics committee reference number

14/26288

Health conditions studied

1

Description of health condition studied

Medical abortion

ICD-10 code

O05

ICD-10 code description

termination of pregnancy

Primary outcomes

1

Description

Pregnancy Exertion

Timepoint

Beginning of the study, every 6 hours up to 36 hours

Method of measurement

dilatation of cervix-contraction and hemorrhage

Secondary outcomes

1

Description

Fever

Timepoint

Every one hour until the last dosage

Method of measurement

Clinical Examination

2

Description

uterus perforation

Timepoint

Every one hour until the last dosage

Method of measurement

Clinical examination by Gynecology resident

3

Description

Amount of bleeding

Timepoint

The start of the intervention up to 36 hours

Method of measurement

Observation and clinical examination

Intervention groups

1

Description

Intervention group: misoprostol 200 mcg tablets (Cytotec) were used vaginally every 6 hours up to 6 times up to 36 hours. Tablets were inserted into the depth of vagina by the midwife. Generic name: MisoprostolBrand name: Cytotec

Category

Treatment - Drugs

2

Description

Control group: misoprostol 200 mcg tablets (Cytotec)

were used orally every 6 hours up to 6 times up to 36 hours. Generic name: Misoprostol Brand name: Cytotec

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Faeze Malak Mohammadi Memar

Street address

Besat Hospital, Keshavarz St., Mardokh Cross Road, Sanandaj, Iran

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Kurdistan University of Medical Sciences

Full name of responsible person

Fardin Gharibi

Street address

Kurdistan University of Medical Sciences, Pasdaran St., Sanandaj, Iran

City

Sanandaj

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, Kurdistan 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

Kurdistan University of Medical Sciences

Full name of responsible person

Faeze Malak Mohammadi Memar

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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Position

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Other areas of specialty/work

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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