Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Nov 2026

Comparative study of effect of misoprostol moistened with normal saline and acetic acid for14 to 26 weeks pregnant women termination.

Protocol summary

Summary

Comparative study on misoprostol moistened with normal saline and acetic acid for second-trimester pregnancy termination. Pregnant women at 14 to 26 weeks of pregnancy who admitted for induced abortion with vaginal misoprostol. Intervention control, 94 patients: (47 patients in intervention group and 47 patient in control group), double blinded (patients and rescearchers), Randomised(by randomised list produced by computer), clinical trial. Misoprostol moistened with acetic acid 400 microgram, q4hour, maximum 5doses to some patients and moistened with normal saline, 400 microgram q4hour, to others will be given randomised. If abortion is occurred: success in abortion at 24 hours and after first dose of misoprostol, side effects, use to abortion interval, doses, in both groups will compare. Misoprostol (prostaglandin E1 analog) moistened with acetic acid, (tablet 200 microgram)400 microgram, 2tablets q4hour, maximum 5doses vaginaly adminestrated for intervention group and moistened with normal salin for control group. Success in termination of pregnancy at first 24 hours, success in termination of pregnancy after first dose, induction interval to delivery, dose of misoprostol used to termination, side effects: nausa, vomiting, shaking.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082635898N1**
Registration date: **2017-10-17, 1396/07/25**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-10-17, 1396/07/25

Registrant information

Name
Bibi Elham Rezaei Askariye
Name of organization / entity
Mashhad university of medical sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of effect of misoprostol moistened with normal saline and acetic acid for14 to 26 weeks pregnant women termination.

Public title

Effect of misoprostol moistened with normal saline and acetic acid for second-trimester pregnancy termination.

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion: pregnant women at 14 to 26 weeks of pregnancy who admitted for induced abortion with

vaginal misoprostol. exclusion criteria :not respond to misoprostol;start of spontaneous abortion; contraindication of medical termination like previa placenta;prostaglandin contraindication like hyper sensivity,asthma, glucoma, cardiovascular disease.

Age
From **9 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size:

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double 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 Mashhad University of Medical Sciences

Street address
Ghoraishy Building, Daneshgah St.

City
Mashhad

Postal code

Approval date
2015-08-19, 1394/05/28

Ethics committee reference number
1394.255

Health conditions studied

1

Description of health condition studied
Induce abortion of second trimester of pregnancy

ICD-10 code
O07.9

ICD-10 code description
Other and unspecified failed attempted abortion, without complication

Primary outcomes

1

Description
Success in termination of pregnancy at first 24 hours.

Timepoint
Every 4 hour from intervention.

Method of measurement
Questionnaire, hour.

2

Description
Success in termination of pregnancy after first dose.

Timepoint
Every 4 hours from intervention.

Method of measurement
Questionnaire, hour.

Secondary outcomes

1

Description
Induction interval to delivery.

Timepoint
During 72 hours from intervention.

Method of measurement
Questionnaire, hour.

2

Description
Dose of misoprostol used to termination.

Timepoint
During 72 hour from intervention.

Method of measurement
Questionnaire

3

Description
Side effects, nausa, vomiting, shaking.

Timepoint
During 48 hours from intervention.

Method of measurement
Questionnaire, check list.

Intervention groups

1

Description
Misoprostol(prostaglandin E1 analog) moistened with acetic acid, (tablet 200 microgram)400 microgram, 2tablets q4hour, maximum 5doses vaginaly adminestrated for intervention group

Category
Treatment - Drugs

2

Description
Misoprostol (prostaglandin E1 analog) moistened with normal salin, (tablet 200 microgram)400 microgram, 2tablets q4hour, maximum 5doses vaginaly adminestrated for control group.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Omolbanin Women Hospital
Full name of responsible person
Dr. Faride Akhlaghi
Street address
Zarine intersection
City
Mashhad

2

Recruitment center
Name of recruitment center
Qaem hospital
Full name of responsible person
Dr. Faride Akhlaghi
Street address
Taghi abad st.
City
Mashhad

3

Recruitment center
Name of recruitment center
Emam reza hospital
Full name of responsible person
Dr. Leili Hafizi
Street address
Emam reza square
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
Ghoraishy Building, Daneshgah St.
City
Mashhad

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, Mashhad 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
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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