Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Randomized clinical trial Comparison of therapeutic effects and side effects of misoprostol moistened with normal saline and acetic acid in induction of therapeutic abortion in the second trimester

Protocol summary

Summary

Objective: comparison of therapeutic effects and side effects of misoprostol moistened with normal saline and acetic acid in induction of therapeutic abortion in the second trimester. Design: randomized, single blind, placebo-controlled, single centre, phase II trial. Setting and conduct: Patients are randomly classified to get vaginal administration of either acetic acid or normal saline moistened misoprostol tablets with a dose schedule of 400 microgram initially and then 200 microgram every 6 hours up to maximum 8 doses over 48 hours. Inclusion criteria: healthy pregnant women in their second trimester of pregnancy (14-20 weeks) with closed cervix that are candidate for therapeutic abortion and agree to participate in this clinical trial. Exclusion criteria: history of more than 2 cesarean section; history of cesarean section with uterine classic or T-shape incision; previous myomectomy; allergy to prostaglandins; severe vaginal bleeding before treatment; anemia Hb less than 7 g/dl); coagulopathy; significant medical disorder(example, active liver disease, cardiovascular disease, renal failure, chronic adrenal failure, disorders requiring corticosteroid therapy); rupture of membrane and vaginitis. Intervention: Misoprostol prescription moistened by either acetic acid or normal saline. Primary outcome measure is complete abortion rate at 24 and 48 hours. Secondary outcome measures are induction abortion interval, failure rate and side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013120315634N1**
Registration date: **2014-05-03, 1393/02/13**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2014-05-03, 1393/02/13

Registrant information

Name

Tayebeh Jahed Bozorgan

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5506 6263

Email address

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-01-27, 1392/11/07

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomized clinical trial Comparison of therapeutic effects and side effects of misoprostol moistened with normal saline and acetic acid in induction of therapeutic abortion in the second trimester

Public title

The effect of misoprostol on the therapeutic abortion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: healthy pregnant women in their second trimester of pregnancy (14-20 weeks) with closed cervix who are candidate for therapeutic abortion and agree to participate in this clinical trial. Exclusion criteria: history of more than 2 cesarean section; history of cesarean section with uterine classic or T-shape incision; previous myomectomy; allergy to prostaglandins; severe vaginal bleeding before treatment; anemia Hb less than 7 g/dl); coagulopathy; significant medical disorder(example, active liver disease, cardiovascular disease, renal failure, chronic adrenal failure, disorders requiring corticosteroid therapy); rupture of membrane and vaginitis.

Age

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

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **91**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 the Shahid Beheshti University of Medical Sciences, Tehran, Iran

Street address

" Yaman Street, Shahid Aarabi Avenue, Shahid Chamran Highway " " Tehran "

City

Tehran

Postal code

Approval date

2014-01-26, 1392/11/06

Ethics committee reference number

SBMU.REC.1392.602

Health conditions studied

1

Description of health condition studied

medical management of second trimester induced abortion

ICD-10 code

O04

ICD-10 code description

Medical abortion

Primary outcomes

1

Description

Complete abortion rate at 24 and 48 hours

Timepoint

every 6 hours

Method of measurement

Questioneaire

Secondary outcomes

1

Description

failure rate

Timepoint

No abortions occurred in 48 hours

Method of measurement

sonography

2

Description

Side effects of drug

Timepoint

Every 6 hours

Method of measurement

Questionnaire

3

Description

Induction abortion interval from insertion of first dose of misoprostol

Timepoint

Every 6 hours

Method of measurement

hour

Intervention groups

1

Description

In intervention group misoprostol tablets is wetted with 3cc acetic acid 5% and then is inserted misoprostol 400 microgram vaginally followed by 200 microgram every 6 hours for maximum 48 hours.

Category
Treatment - Drugs

2

Description
In controlled group misoprostol is wetted with 3cc normal saline and then is inserted misoprostol 400 microgram vaginally followed by 200 microgram every 6 hours for maximum 48 hours.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdieh Hospital
Full name of responsible person
Nayereh Rahmati
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor for Research, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
'' Sahid Beheshti University of Medical Sciences, Yaman Street, Shahid Aarabi Avenue, Shahid Chamran Highway
City
Tehran
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, Shahid Beheshti 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
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Person responsible for updating data

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Nayereh Rahmati
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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