# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

28 Jun 2026

## Comparison of misoprostol administration in second trimester pregnancy termination

### Protocol summary

**Summary**

This study was aimed to compare the therapeutic results of two different regimen of vaginal Misoprostol (every 6 hours vs 12 hours) on the second trimester pregnancy termination. This randomized controlled trial was carried out at Kosar Hospital affiliated to Qazvin University of Medical Sciences and Health Services (Iran) in 2007. 140 pregnant women between 14-28 weeks of gestational age undergoing termination of pregnancy because of fetal anomaly, IUFD, PROM, severe oligohydramnious, or maternal diseases were randomly assigned into two equal groups. The first group received 400µg vaginal Misoprostol every 6 hours and the second group received the same dose of Misoprostol every 12 hours. Primary outcome was duration of induction time after administration of vaginal Misoprostol.

### General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT138810193025N1**
Registration date: **2010-03-06, 1388/12/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2010-03-06, 1388/12/15

**Registrant information**

**Name**
Farideh Movahed
**Name of organization / entity**
Qazvin University of Medical Sciences and Health Services
**Country**
Iran (Islamic Republic of)
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+98 28 1335 0307
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**Recruitment status**

**Recruitment complete**

**Funding source**
Vice-chancellor for Research, Qazvin University of Medical Sciences and Health Services, Iran

**Expected recruitment start date**

2007-03-22, 1386/01/02

**Expected recruitment end date**

2008-01-20, 1386/10/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of misoprostol administration in second trimester pregnancy termination

**Public title**

Comparison of misoprostol administration in second trimester pregnancy termination

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: pregnant women between 14 -28 weeks of gestation undergoing termination of pregnancy because of fetal anomalies, IUFD, PROM, severe Oligohydraminious, maternal diseases. Exclusion criteria: uncontrolled heart diseases, acute asthmatic attack, glaucoma, history of cesarean section more than two times or classic cesarean section, previous incision on uterus, parity>6

**Age**

From **18 years** old to **40 years** old

**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **140**
**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**
Vice-chancellor for Research, Qazvin University of Medical Sciences and Health Services, Iran
**Street address**
Bahonar Blvd, Qazvin
**City**
Qazvin
**Postal code**
**Approval date**
2008-09-04, 1387/06/14
**Ethics committee reference number**
28/20/1128

## Health conditions studied

**1**

**Description of health condition studied**
Medical abortion
**ICD-10 code**
O04
**ICD-10 code description**
Medical abortion

## Primary outcomes

**1**

**Description**
Interval between administeration of drug and expulsion of fetus
**Timepoint**
24 hours, 48 hours after intervention
**Method of measurement**
Duration, in hours

## Secondary outcomes

**1**

**Description**
Total dose of misoprostol administeration in termination of pregnancy
**Timepoint**
every 6 hours in teh first group, every 12 hours in the second group
**Method of measurement**
Total dose administered, in microgram

## Intervention groups

**1**

**Description**
Misoprostol, 400 mg, vaginal, every 6 hours, within 48 hours
**Category**
Treatment - Drugs

**2**

**Description**
Misoprostol, 400 mg, vaginal, every 12 hours, within 48 hours
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Kosar hospital, Qazvin
**Full name of responsible person**
**Street address**
**City**
Qazvin

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice-chancellor for Research, Qazvin University of Medical Sciences and Health Services, Iran
**Full name of responsible person**
Dr Saeed Assefzadeh
**Street address**
Shahid Bahonar Blvd, Qazvin
**City**
Qazvin

**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, Qazvin University of Medical Sciences and Health Services, Iran
**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**
Vice-chancellor for Research, Qazvin University of Medical Sciences and Health Services, Iran
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**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

## 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*