

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison between the oral and vaginal Misoprostol effects on Pregnancy Termination in Second

Protocol summary

Summary

Objective : The purpose of this study was to compare the efficacy of two different misoprostol diets in second trimester pregnancy termination . Methods : 60 consenting women who were on 14 to 28 weeks of gestational age with indications of pregnancy termination due to missed abortion ,fetal abnormality ,fetal death and PROM per ultrasound twice were randomly allocated in two equal groups of 30 persons to receive either vaginal or oral misoprostol .Dosage diet was 400 µg as an initial ones which was followed by another 400 µg up to 3 dosage (1200 µg) if it was needed . The due date of termination was 48 hours after the last dosage.Otherwise,the oxytocin or surgery methods was used. It was recommended to refer two weeks later for ultrasound to investigate of pregnancy residual and determine weather D&C was needed or not.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706061106N1**

Registration date: **2008-09-27, 1387/07/06**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2008-09-27, 1387/07/06

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

KASHAN UNIVERSITY OF MEDICAL SCIENCES

Expected recruitment start date

2006-08-22, 1385/05/31

Expected recruitment end date

2007-03-23, 1386/01/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the oral and vaginal Misoprostol effects on Pregnancy Termination in Second

Public title

Comparison between the oral and vaginal Misoprostol effects on Pregnancy Termination in Second

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Pregnant women in(14- 28 week) were candidate in termination because of missed abortion ,fetal abnormality ,fetal death and premature rupture of membrane. Exclusion criteria :Uncontrolled seizure, asthma,glucohema,hypertension ,COPD,mitral stenosis,inflammatory intestinal disease,history of allergy to PG E1.

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 60

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

KASHAN UNIVERSITY OF MEDICAL SCIENCES

Street address

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OF RESEARCH

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87155-111

Approval date

empty

Ethics committee reference number

29-5-1-7409

Health conditions studied

1

Description of health condition studied

pregnancy termination in Second Trimester

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

PREGNANCY TERMINATION

Timepoint

begining of study -every 6 hours up to 48 hours

Method of measurement

dilatation of cervix-contraction and hemorrhage

Secondary outcomes

1

Description

Gastrointestinal disorders

Timepoint

every one hours until the last dosage

Method of measurement

Clinical examination

2

Description

fever

Timepoint

every one hours until the last dosage

Method of measurement

vital sign

Intervention groups

1

Description

Intervention:vaginal misoprostol

Category

empty

2

Description

Control: oral misoprostol

Category

empty

Recruitment centers

1

Recruitment center

Name of recruitment center

shabihkhani hospital

Full name of responsible person

dr mohsen dibaji

Street address

kashan - beheshti hospital

City

kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

kashan university of medical sciences

Full name of responsible person

dr golam ali hamidi

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kashan-kashan university of medical sciences- deputy
of research

City
kashan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
kashan 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

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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