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 ultrosound 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 reffer 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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City
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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
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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