Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Effect of sublingual, vaginal and oral misoprostol on treatment of missed abortion in the pregnant women in the first trimester; Comparative study

Protocol summary

Summary

The aim of this study is comparison of three different routes of sublingual, oral and vaginal misoprostol in missed abortion during the first trimester of pregnancy. In this randomized clinical trial, 195 patients candidate for abortion, hospitalized in Mobini Sabzevar in 2014 were randomly allocated to three groups of sublingual, oral and vaginal misoprostol. Patients in all three groups, will treat with 600ug dose every 6 hours (maximum 4 doses). Patient will be controlled at least 24 hours for probable drug side effects and severity of vaginal bleeding. All patients will be visited again next week. Some of the inclusion criteria are gestational age less than 14 weeks and confirmation of the need for pregnancy termination by ultrasound. Some exclusion criteria are vaginal bleeding and emergency need for surgery to pregnancy termination. This study will be determinate the best route of misoprostol administration, probable complications and patient Satisfaction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101015905N2**
Registration date: **2014-12-11, 1393/09/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-12-11, 1393/09/20

Registrant information

Name

Mahbobe Mohebbi

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 51 1386 1959

Email address

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Recruitment status

Recruitment complete

Funding source

Sabzevar University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-08-21, 1394/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of sublingual, vaginal and oral misoprostol on treatment of missed abortion in the pregnant women in the first trimester; Comparative study

Public title

Effect of misoprostol on treatment of missed abortion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria are gestational age less than 14 weeks; confirmation of the need for pregnancy termination by ultrasound. Exclusion criteria are the vaginal bleeding; emergency need for surgery to pregnancy termination; anemia; Coagulation disorders or taking anticoagulant;, history of diseases (liver, kidney and heart); history of allergy to prostaglandin; smoking; inflammatory diseases and hemoglobin less than 9 g/dl.

Age

From **16 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **195**

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
Sabzevar University of Medical Sciences

Street address
Next to the police station to Shahroud road, Sabzevar.

City
Sabzevar

Postal code

Approval date
2014-07-14, 1393/04/23

Ethics committee reference number
medsab.Rec.93020

Health conditions studied

1

Description of health condition studied
missed abortion

ICD-10 code
O02.1

ICD-10 code description
Early fetal death with retention of dead fetus

Primary outcomes

1

Description
Proportion of compelete abortion

Timepoint
Compelete abortion during 7 days

Method of measurement
Complete evacuation of the uterus by ultrasound

Secondary outcomes

1

Description
The intensity and duration of bleeding

Timepoint
Up to 7 days

Method of measurement
Higham chart

Intervention groups

1

Description
The intervention in oral group will be done by administering 600 µg of misoprostol every 6 hours (up to 4 doses) orally in pregnant women with missed abortion.

Category
Treatment - Drugs

2

Description
The intervention in vaginal group will be done by administering 600 µg of misoprostol every 6 hours (up to 4 doses) vaginally in pregnant women with missed abortion.

Category
Treatment - Drugs

3

Description
The intervention in sublingual group will be done by administering 600 µg of misoprostol every 6 hours (up to 4 doses) vaginally in pregnant women with missed abortion.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mobini Hospital

Full name of responsible person
Dr Sewizi

Street address
Mobini Hospital, Sabzevar, Razavi Qorasan

City
Sabzevar

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Sabzear University of Medical Science
Full name of responsible person
Rahim Akrami
Street address
Next to the police station to Shahroud road, Sabzevar.
City
Sabzear
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Sabzear University of Medical Science
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
Member of research committee in Sabzevar University of Medical Sciences
Full name of responsible person
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Position
Master of nursing
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Person responsible for scientific inquiries

Contact
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Person responsible for updating data

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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