

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)

Phone

+98 51 1386 1959

Email address

mohebbi_mhb@yahoo.com

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 complete abortion

Timepoint

Complete 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

Sabzevar University of Medical Science

Full name of responsible person

Rahim Akrami

Street address

Next to the police station to Shahroud road, Sabzevar.

City

Sabzevar

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Sabzevar 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

Mahbobe Mohebbi

Position

Master of nursing

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Faculty member of sabzevar University of Medical Sciences

Full name of responsible person

Dr Behnaz Sewzie

Position

Gynecologist

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Person responsible for updating data

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Fateme Borzoee

Position

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Other areas of specialty/work**Street address**

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Web page address

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