Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of vaginal versus sublingual misoprostol in medical induction of missed abortions: a randomized clinical trial

Protocol summary

Summary

Objectives: To compare the effect of vaginal versus sublingual misoprostol in medical induction of missed abortions. Design: A randomized clinical trial. Setting and conduct: The eligible women with missed abortions who will refer to Fatemieh Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 40 years; gestational age 6 to 14 weeks; missed abortions. Exclusion criteria: Previous cesarean; systemic diseases. Intervention group 1: Tablet misoprostol 600 micgr sublingually single dose and if bleeding does not begin after 6 hours, the same dose will be repeated. Intervention group 2: Tablet misoprostol 600 micgr vaginally single dose and if bleeding does not begin after 6 hours, the same dose will be repeated. Primary outcome: (a) bleeding and abortion 3, 6, and 12 hours after intervention thorough physical examination; (b) remaining vestiges of pregnancy or incomplete abortion 12 hours after intervention by sonography. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201704179014N159**
Registration date: **2017-04-30, 1396/02/10**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-04-30, 1396/02/10

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-05-05, 1396/02/15

Expected recruitment end date

2018-03-06, 1396/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of vaginal versus sublingual misoprostol in medical induction of missed abortions: a randomized clinical trial

Public title

Comparison of the effect of vaginal versus sublingual misoprostol in medical induction of missed abortions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 40 years; gestational age 6 to 14 weeks; missed abortions. Exclusion criteria: Previous cesarean; systemic diseases.

Age
From **18 years** old to **40 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Not possible.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences
Street address
Vice-chancellor for Research the Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
6517838695
Approval date
2016-04-23, 1395/02/04
Ethics committee reference number
IR.UMSHA.REC.1395.30

Health conditions studied

1

Description of health condition studied
Missed abortion
ICD-10 code
O02.1
ICD-10 code description
Missed abortion

Primary outcomes

1

Description
bleeding and abortion
Timepoint
3, 6, and 12 hours after intervention
Method of measurement
thorough physical examination

2

Description
remaining vestiges of pregnancy or incomplete abortion
Timepoint
12 hours after intervention
Method of measurement
by sonography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Tablet misoprostol 600 micgr sublingually single dose and if bleeding does not begin after 6 hours, the same dose will be repeated.
Category
Treatment - Drugs

2

Description
Intervention group 2: Tablet misoprostol 600 micgr vaginally single dose and if bleeding does not begin after 6 hours, the same dose will be repeated.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Mina Ajand
Street address
Fatemieh Hospital, Pasdaran Ave.
City
Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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Hamadan

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 and Technology, Hamadan 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

Contact

Name of organization / entity

Fatemieh Hospital

Full name of responsible person

Mina Ajand

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Medical Student

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Person responsible for updating data

Contact

Name of organization / entity

Department of Epidemiology

Full name of responsible person

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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