Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 81 1838 0090

Email address

poorolajal@umsha.ac.ir

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
City
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
Position
Medical Student
Other areas of specialty/work
Street address
Fatemieh Hospital, Pasdaran Ave.
City
Hamadan
Postal code
Phone
+98 81 3828 3939
Fax
Email
ajandmina@Gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Fatemieh Hospital
Full name of responsible person
Mina Ajand
Position
Medical Student
Other areas of specialty/work
Street address
Fatemieh Hospital, Pasdaran Ave.
City
Hamadan
Postal code
Phone
+98 81 3828 3939
Fax
Email
ajandmina@Gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Department of Epidemiology
Full name of responsible person
Dr Jalal Poorolajal
Position
Associate Professor
Other areas of specialty/work
Street address
School of Public Health, Hamadan University of Medical Sciences, Shahid Fahmideh Ave
City
Hamadan
Postal code
6517838695
Phone
+98 81 3838 0090
Fax
Email
poorolajal@umsha.ac.ir
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