Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Efficacy of vaginal Misoprostol, Isosorbide Mononitrate and giving time without medication for preoperative cervical ripening in under 20 weeks abortion

Protocol summary

Study aim
Comparison of the effect of vaginal misoprostol and isosorbide menonitrate and control group on cervical preparation in less than 20-week abortions in Alavi hospital in Ardabil

Design
A total of 120 patients with miscarriage will be selected. The clinical trial will have a control group with parallel group design. Randomization and blinding will not be used in this study. The study will be a phase 3 clinical trial.

Settings and conduct
The study site will be Alavi Hospital in Ardabil.

Participants/Inclusion and exclusion criteria
Inclusion criteria: gestation age under 20 weeks; candidate for abortion due to proved fetal death confirmed with sonography; severe abnormality in which the fetus could not survive. Exclusion criterion: certain underlying disease such as cancer

Intervention groups
Intervention group 1: Vaginal misoprostol, 200 µg every 6 hours until 13 weeks of gestation and 200 µg every 6 to 12 hours from 14 weeks to 20 weeks of gestation. Intervention group 2: placing 40 milligrams of isosorbide mononitrate in the posterior vaginal fornix (it will be continued after every 6 hours to 12 hours of follow-up if needed). Control group: We give a chance for 12 2 hours to spontaneous cervical softening or spontaneous disposal. The patient will be examined regularly every 6 hours.

Main outcome variables
Cervical preparation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190901044658N1**
Registration date: **2019-12-07, 1398/09/16**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-07, 1398/09/16**
Update count: **0**

Registration date
2019-12-07, 1398/09/16

Registrant information

Name
Shahla Farzipour

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 45 3323 0739

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m.rezayi@arums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-22, 1398/04/01

Expected recruitment end date
2019-12-22, 1398/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of vaginal Misoprostol, Isosorbide Mononitrate and giving time without medication for preoperative

cervical ripening in under 20 weeks abortion

Public title
The effect of vaginal misoprostol and isosorbide mononitrate on under 20 week miscarriages
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Gestational age under 20 weeks candidate for abortion due to proved fetal death confirmed by sonography severe abnormality in which the fetus is not viable
Exclusion criteria:
Certain underlying disease such as cancer
Age
From **15 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Not 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
Ethics committee of Ardabil University of Medical Sciences
Street address
No. 1, Moallem avenue
City
Ardabil
Province
Ardabil
Postal code
5613843793
Approval date
2019-05-27, 1398/03/06
Ethics committee reference number
IR.ARUMS.REC.1398.277

Health conditions studied

1

Description of health condition studied
Cervix Preparation for Abortion
ICD-10 code
O02.1
ICD-10 code description
Missed abortion

Primary outcomes

1

Description
The time of the cervix preparation for abortion
Timepoint
The patient will be examined regularly every 6 hours, and if the fetus is not discharged, the drug will be repeated after 6 to 12 hours.
Method of measurement
It will be a clinical and cervical examination by a resident resident.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: The first group will be given vaginal misoprostol, 200 µg every 6 hours up to 13 weeks of gestational age and 200 µg every 6-12 hours from 14 to 20 weeks of gestational age.The drug will be given every 6 to 12 hours up to 3 doses if needed.
Category
Treatment - Drugs

2

Description
Intervention group2: In the second group, 40 milligrams of isosorbide menonitrate will be placed in the posterior vaginal fornix and the same dose will be prescribed every 6 to 12 hours after the examination. The drug will be repeated every 6 to 12 hours up to 3 dose.
Category
Treatment - Drugs

3

Description
Control group: The control group was given 12 hours time to reach softening the cervix or spontaneous dispose of the fetus and was not prescribed medication.
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Alavi hospital
Full name of responsible person
Mahsa Rezayi
Street address
No. 1, Moallem avenue
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Ardabil
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+98 45 3323 0739
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meisamfooladi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Parvaneh Naftchi
Street address
No. 1, Daneshgah avenue
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meisamfooladi@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ardabil University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Shahla Farzipour
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

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Position
Assistant
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
The questionnaires will be available anonymously and just with a document number.
When the data will become available and for how long
The time to access the information will be after the study is completed.
To whom data/document is available
University professors
Under which criteria data/document could be used
The data will be available anonymously and with specified codes and in accordance with ethics committee rules.
From where data/document is obtainable
Ms. Naftachi will be contacted to access the data. They will provide the information with the approval of the university.
What processes are involved for a request to access data/document
Contact with Ms. Naftchi and providing university Approval.
Comments