Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of the effect of Misoprostol and Diplen with Misoprostol in cervical priming in the first and second trimesters

Protocol summary

Study aim
Comparison of the effect of Misoprostol and Dilapen with Misoprostol during cervical preparation in first and second trimesters. Comparison of the effect of Misoprostol and Dilapen with Misoprostrol on cervical dilatation in first and second trimester abortions.

Design
Clinical trial with control group, with parallel group, double-blind, randomized, phase 3, on 196 patients. R random function of R software was used for randomization.

Settings and conduct
Patients are randomly divided into two groups.The first group of misoprostol is placed 4 hours before surgery and the second group of dilapen is placed 24 hours before surgery and 4 hours before surgery. After general anesthesia, all evaluations of cervical by The blind researcher is done, then the curettage is done and the curettage products are sent for pathology

Participants/Inclusion and exclusion criteria
Inclusion criteria: mothers over the age of 18, a gestational age of less than or equal to 24 weeks based on the date of the last menstrual period (LMP), and an ultrasound of the first 3 months of pregnancy Exclusion criteria: patient dissatisfaction to participate in the study, patients under 18 years of age, contraindications to the use of misoprostol (drug allergy, active asthma, heart disease, renal failure or glaucoma), active genital infection, structural disorders of the uterus and bladder, cancer Cervical and surgical history of cervical cancer

Intervention groups
The first group is received for the preparation of cervical dilapine with misoprostol, and the second group is treated with misoprostol

Main outcome variables
Cervix preparation time Feeling the patient's discomfort based on the five-digit criterion Dilatation and cervical consistency based on the surgeon's examination according to the five-digit criterion

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200603047648N1**
Registration date: **2020-07-13, 1399/04/23**
Registration timing: **prospective**

Last update: **2020-07-13, 1399/04/23**
Update count: **0**

Registration date
2020-07-13, 1399/04/23

Registrant information
Name
Naeeme Morovati
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-09-22, 1399/07/01
Expected recruitment end date
2021-09-23, 1400/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Comparison of the effect of Misoprostol and Diplen with Misoprostol in cervical priming in the first and second trimesters

Public title
Mesoprostol and Dilapen in the preparation of the cervix for abortion
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years for mothers Less or equal pregnancy age 24 weeks based on (LMP) and ultrasound of the first 3 months of pregnancy Patient satisfaction to participate in the study Legal permission for abortion is from the relevant authorities
Exclusion criteria:
Patients under 18 years of age Contraindications to the use of misoprostol (drug allergy, active asthma, heart disease, renal failure or glaucoma) Active genital infection Structural disorders of the uterus and bladder Cervical cancer History of cervical surgery
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor

Sample size
Target sample size: **196**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, random allocation of individuals to two groups of intervention and current treatment was performed using Balanced bloch randomization technique. Using R software to generate random number chains 1 to 6 (the number of possible states for placement in blocks) Until the volume of the sample was reached. Preparation of random allocation sequences of individuals and placing them in sealed envelopes (sealed) and numbered with a 5-digit serial number by the third person who plays a role in designing the study. Has not, has been done
Blinding (investigator's opinion)
Double blinded
Blinding description
In the treatment group, in addition to receiving vaginal diazepam mesoprostol, it is vaginally placed by a specialist doctor, and in the control group, only mesoprostol is received. After the procedure, patients will be examined by 2 blind researchers who do not know to whom dilapen is placed. Who has only used misoprostol. Patients will be examined by two researchers in terms of postoperative complications. The patient will then be hospitalized for side effects after surgery and the consequences of the procedure. The patient's opinion is checked by a student (specific to this task) that the student does not know who received the diplopen and who did not receive it and records all the consequences. In fact, neither the researcher nor the evaluator of the consequences of how patients are divided
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Alborz University Of medical Sciences
Street address
Saffarian Alley, Golshahr
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Alborz
Postal code
3198764653
Approval date
2020-05-26, 1399/03/06
Ethics committee reference number
IR.ABZUMS.REC.1399.063

Health conditions studied

1

Description of health condition studied
Medical abortion in first and second trimester
ICD-10 code
O04.80
ICD-10 code description
(Induced) termination of pregnancy with unspecified complications

Primary outcomes

1

Description
Cervical dilatation rate
Timepoint
Before surgery and after general anesthesia
Method of measurement
Examination by a specialist

2

Description

Feeling sick

Timepoint

Before surgery and after general anesthesia

Method of measurement

Examination by a specialist doctor based on a five-digit criterion (without discomfort, with discomfort, relatively uncomfortable, very uncomfortable, unbearable)

3

Description

Servicing preparation time

Timepoint

After receiving the drug until the start of surgery

Method of measurement

Examination by a specialist

Secondary outcomes

1

Description

Side effects(include vaginal pain, pressure on the bladder, diarrhea and vaginal bleeding, and incomplete miscarriage.)

Timepoint

Before general anesthesia, after the procedure and the patient regained consciousness

Method of measurement

Examination by a specialist doctor, ultrasound (if you have symptoms in favor of incomplete abortion once before discharge)

2

Description

Cervical consistency

Timepoint

Before surgery and after general anesthesia

Method of measurement

Examination by a specialist doctor based on three-digit criteria (according to the surgeon, soft, medium, hard)

Intervention groups

1

Description

Control group: Control group: In the control group, to prepare the cervix, 400 micrograms of misoprostol will be placed vaginally by a gynecologist 4 hours before surgery. Mesoprostol is an analogue of prostaglandin E1, which is the best option for cervical preparation studies in terms of speed, function and cost.

Category

Treatment - Drugs

2

Description

Intervention group: Intervention group: In this group, to prepare the cervix, 24 hours before the surgery, a diplopene is placed vaginally by the obstetrician and gynecologist for the patient. The cervix becomes vaginal). 4 hours before surgery, 400 micrograms of misoprostol will be vaginally placed by a gynecologist (exactly as done for the control group). The synergistic effect of the two can be examined together

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Kamali Hospital

Full name of responsible person

Bita Badehnoosh

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj University of Medical Sciences

Proportion provided by this source

100

Public or private sector
Private
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
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Bita Badehnoosh
Position
Assistant professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available