

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

Comparison of the effect of Misoprostol and Dilapen 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 Misoprostol 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

Country

Iran (Islamic Republic of)

Phone

+98 26 8566 8514

Email address

naeeme.mrv@gmail.com

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 Dilpen 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 block 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

City

Karaj

Province

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

diplovene 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

Street address

Alborz university of medical science, Saffarian Alley, Golshahr

City

Karaj

Province

Alborz

Postal code

4156853445

Phone

+98 26 4158 6658

Email

badehnoosh@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mostafa Ghorbani

Street address

Saffarian Alley, Golshar blvd

City

Karaj

Province

Alborz

Postal code

3198764653

Phone

+98 26 3464 3705

Email

Research@abzums.ac.ir

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

Karaj

Province

Alborz

Postal code

4156853445

Phone

0098 26 4158665

Email

badehnoosh@abzums.ac.ir

Person responsible for general inquiries**Contact****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Bitah Badehnoosh

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Kamali hospital ,Kamali Ave, shohada sq, Beheshti
blvd

City

Karaj

Province

Alborz

Postal code

4156853445

Phone

+98 26 4158 6658

Email

badehnoosh@abzums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Naeeme morovati

Position

Medical intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Kamali Hospital , Kamali Ave , Shohada Sq , Beheshti
Alley

City

Karaj

Province

Alborz

Postal code

3134877179

Phone

+98 26 3222 2021

Email

naeeme.mrv@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Bitah Badehnoosh

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Alborz university of medical sciences , Saffarian Alley
, Golshahr

City**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