Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the efficacy of dilapane-S gel in comparison with misoprostol during pre-hysteroscopic cervical preparation

Protocol summary

Study aim
Evaluation of the efficacy of Dilapan S gel in comparison with misoprostol for cervical preparation before hysteroscopy

Design
It is a double-blind clinical trial performed on 120 patients undergoing hysteroscopy. Randomization is performed simply and patients are divided into control and control groups with parallel groups

Settings and conduct
This study will be performed in Hazrat Rasool Akram Hospital based on the prospective method. The study population is female patients referred to the gynecology clinic in the mentioned hospital who are candidates for hysteroscopic surgery. According to the sample size calculations, 120 patients with the mentioned conditions were selected and after providing the necessary explanations about this The plan will receive written consent.

Participants/Inclusion and exclusion criteria
Inclusion criteria included postmenopausal women (at least more than 1 year after the last menstrual cycle) or Nolipar or Multipar who have no history of normal delivery who are candidates for hysteroscopic surgery due to uterine myoma of uterine polyp, increased endometrial thickness confirmed by ultrasound or Abnormal vaginal bleeding. Exclusion criteria are contraindications to hysteroscopy, recent or current pelvic infection, previous surgery on the cervix, confirmed cervical or breast malignancies, history of vaginal delivery, sensitivity to misoprostol and prostaglandins.

Intervention groups
Patients in the intervention group underwent dilapane S (3MM * 55MM) 6 hours before the operation and vaginal misoprostol was placed 6 hours before the operation in the control group

Main outcome variables
Dilatation, pain intensity and bleeding of the patient after hysteroscopy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191123045476N2**
Registration date: **2021-02-19, 1399/12/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-02-19, 1399/12/01**
Update count: **0**

Registration date
2021-02-19, 1399/12/01

Registrant information

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Samaneh Rokhgireh

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-22, 1399/07/01

Expected recruitment end date
2021-03-19, 1399/12/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the efficacy of dilapane-S gel in comparison with misoprostol during pre-hysteroscopic cervical preparation

Public title
Evaluation of the effect of Dilapane-S gel on preoperative cervical preparation

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Postmenopausal women (at least 1 year after the last menstrual cycle) or Nolipar or Multipar who have no history of natural childbirth are candidates for hysteroscopic surgery due to uterine myoma and uterine polyp. Postmenopausal women (at least more than 1 year after the last menstrual cycle) or Nolie Par or Multipar who have no history of normal delivery are candidates for hysteroscopic surgery due to increased endometrial thickness confirmed by ultrasound or abnormal vaginal bleeding

Exclusion criteria:
Contraindications to hysteroscopy Recent or current pelvic infections Previous cervical surgery Confirmed cervical or breast malignancies Vaginal delivery history Hypersensitivity to misoprostol and prostaglandins

Age
From **49 years** old to **52 years** old

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, restricted randomization sampling method is used that the study groups have equal sample size. Random allocation rule is one of the limited random sampling methods used in the present study. And patients are equally divided into two groups. On how to randomize, researchers first determine a total sample size, then randomly assign a set of them to group A and the rest to group B. For example, in a study with a sample size of 200 people, 100 balls For intervention group A and 100 balls, for intervention group B, it is placed in a lottery container and then the balls are randomly removed from the container without replacement and the created sequence is recorded. This method is used for two or more group trials.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients in the intervention group are placed with dilapane 6 hours before hysteroscopy. 6 hours later, before hysteroscopy, dilapane is removed and the patient is transferred to the operating room. In the control group, 6 hours before surgery (the night before surgery) will receive 200 micrograms of vaginal misoprostol tablets (Sami Saz Pharmaceutical Company). How medications are prescribed to the surgeon who evaluates the outcome will be kept secret. The analyzer is also unaware of the type of medication being administered.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences

Street address
Sattar Khan St., Maziar Mansouri St., Rasoul Akram Hospital

City
Tehran

Province
Tehran

Postal code
1445613131

Approval date
2020-11-07, 1399/08/17

Ethics committee reference number
IR.IUMS.REC.1399.764

2

Ethics committee

Name of ethics committee
Ethics Committee of Iran University of Medical Sciences

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Province
Tehran

Postal code
1445613131

Approval date
2020-11-07, 1399/08/17

Ethics committee reference number
IR.IUMS.REC.1399.764

Health conditions studied

1

Description of health condition studied
Hysteroscopy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Cervical dilatation
Timepoint
The time required to start dilatation until the arrival of a hysteroscope or resectoscope will be recorded as a conclusion
Method of measurement
Initially, the initial condition of the cervix, including the position and softness of the cervix, will be evaluated observably. No resistance is passed as dilatation before hysteroscopy and will be recorded as a conclusion. Our ultimate goal will be dilatation with Hagar number 10-8.

Secondary outcomes

1

Description
Severe pain and bleeding after hysteroscopy
Timepoint
Immediately after the patient regains consciousness
Method of measurement
visual analog scale, which includes a table to evaluate the patient's pain and bleeding in the form of zero indicates painless and ten indicates severe and unbearable pain and bleeding.

Intervention groups

1

Description
Intervention group: Patients in the intervention group undergoing placement with Dilapane S (3MM * 55MM) made by Kardan Elixir Company, 6 hours before hysteroscopy, which is first moistened with sterile water or saline, and then take the Dilapane S handle gently and without Excess pressure is applied to the cervical canal only when it passes through the external and internal holes. The Dilapan handle should be placed around the external hole and not go beyond it, and 6 hours later and before hysteroscopy to remove the Dilapan S handle only with Forceps are taken and a continuous downward pull is applied along the longitudinal axis of the dilator, which makes it easy and painless to exit.
Category
Treatment - Devices

2

Description
Control group: In the control group, 6 hours before surgery (the night before surgery) will receive 200 micrograms of vaginal misoprostol tablets (Sami Saz Pharmaceutical Company).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool Akram Hospital
Full name of responsible person
Samaneh Rokhgireh
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Sponsors / Funding sources

1

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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Samaneh Rokhgireh
Position
Associate professor
Latest degree
Specialist
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Following the publication of the article, confidential information such as patient profile and Hospital, ... deletion and other information Will be made available to researchers
When the data will become available and for how long
After publishing the article
To whom data/document is available
Medical specialists
Under which criteria data/document could be used
Medical professionals can turn to data for research purposes gain access
From where data/document is obtainable
Refer to the email of the responsible author
What processes are involved for a request to access data/document
Official and academic email to the responsible author
Comments