

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The surveya comparative study on the effect of Nitroglycerin and Misoprostol on cervical ripening before first-trimester curettage in women (a clinical trial)

Protocol summary

Study aim

comparative study on effect of Nitroglycerin and Misoprostol on cervical ripening before curettage in women for make easy the surgery and reduce the outcome.

Design

This phase 3 double-blind clinical trial study is performed on 170 women candidates for curettage. First, people were selected gradually and 85 people were randomly selected by Sealed Envelope Ltd. online randomization service. 2019 will be in Group A and 85 people in Group B. Women in group A with a vaginal trinitroglycerin tablet of 400 micrograms, Women in group B receive misoprostol 400 micrograms vaginally according to the national protocol.

Settings and conduct

170 women referring to Al-Zahra Hospital will be enrolled during the year 1400. Women in group A will receive 400 micrograms trinitroglycerin vaginally by a female assistant, and women will receive 400 micrograms of misoprostol vaginally . 4 hours after, patients will be transferred for curettage. Rejection with a bogey of up to 8 mm indicates a response to the drug and if not rejected, be considered as a negative outcome.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: un ripe cervix, complete satisfaction with the study, gestational age less than 14 weeks, normal vital signs, no drug use, no bleeding, coagulation disorders, active liver disease, cardiovascular disease, Uncontrolled seizures, history of glaucoma, adrenal disease, reason for termination of pregnancy (missed abortion, anembryonic pregnancy, medical abortion) not Inclusion criteria include: Patients who wish to have a medical abortion and are not candidates for curettage surgery. Women who have more than one history of uterine scarring.

Intervention groups

Group A: 85 people will receive 400 mg of nitroglycerin vaginally. Group B 85 people will receive 400 mg of misoprostol vaginally

Main outcome variables

Cervical ripening

General information

Reason for update

Acronym

Nitroglycerin and Misoprostol on cervical ripening

IRCT registration information

IRCT registration number: **IRCT20210510051247N1**

Registration date: **2021-05-16, 1400/02/26**

Registration timing: **prospective**

Last update: **2021-05-16, 1400/02/26**

Update count: **0**

Registration date

2021-05-16, 1400/02/26

Registrant information

Name

fatemeh hosseinzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3336 9224

Email address

drfatemehhosseinzadeh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The surveya comparative study on the effect of Nitroglycerin and Misoprostol oncervical ripening before first-trimester curettage in women (aclinical trial)

Public title
Comparative study oneffect of Nitroglycerin and Misoprostol oncervical ripeningbefore curettage in women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
After obtaining full consent to participate in the study, pregnant women are candidates for curettage with a gestational age of less than 14 weeks who have a reason for termination of pregnancy (missed abortion, medical abortion) based on the case file documents And have normal vital signs including no fever(less than 38 ° C), normal heart rate between 70 and 100 and systolic blood pressure between 100 and 130. Also have a history of uterine scarring at most once, no drug abuse, no bleeding (based on initial examination)Lack of coagulation disorder or recent history of anticoagulants, no active liver disease, cardiovascular disease, uncontrolled seizures, history of glaucoma, adrenal insufficiency are the conditions for inclusion in the study.
Exclusion criteria:
Patients who wish to have a medical abortion and are not candidates for curettage surgery for any reason. Women who have more than one history of uterine scarring are not included in the study

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **170**

Randomization (investigator's opinion)
Randomized

Randomization description
All eligible individuals will be divided into two groups A (nitroglycerin recipient) and B (Misoprostol recipient) using block randomization method with 4 and 6 block sizes. An online randomization service was used to generate the list.
<https://www.sealedenvelope.com/simple-randomiser/v1/li>

sts

Blinding (investigator's opinion)
Double blinded

Blinding description
After admitting patients to the hospital, first and second year residents examine and takenbiographies of women, if they are eligible to enter the study, based on the online randomization list available to the senior residents of a women's ward, a code is assigned to each patient. The basis of that code is in group A or B. Finally, 85 people in group A and 85 people in group B will be placed.In group A, receives 400 mg of trinitroglycerine equivalent to a gelatin capsule vaginally, and group B receives misoprostol 400 mg. The equivalent in group B200 mg tablets is given vaginally according to the national protocol. (Due to vaginal use and lithotomy positionwhile receiving the drug, it is not possible for the patient to see the drug. Because the medication is given to the patient by another person (first and second year resident), the researcher (evaluator) is unaware of the status of the groups. 4 hours after taking the drug dose (once), patients in both groups will be transferred to the operating room for curettage. Rejection with bogeyHegar up to 8 mm indicates the response to the drug and its success and without the need for Mechanical dilation will be performed. The second examination of patients is re-examined by a senior resident who is unaware of the treatment group. In operating room if bogeyHegar 8 mm is not passed through cervix, they will be considered as negative and unsuccessful results of the treatment method used and mechanical dilation performed before curettage. In whole stage of research the researcher is unaware of therapyin both groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Guilan University of Medical Sciences

Street address
Research vice-chancellorship Building, in front of 17-Shahrivar Hospital, ShahidSiadati St., Namjoo Ave., Rasht, Guilan, IRAN

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Rasht

Province
Guilan

Postal code
41446-66949

Approval date

2021-05-05, 1400/02/15

Ethics committee reference number

IR.GUMS.REC.1400.044

Health conditions studied

1

Description of health condition studied

Pregnancy ,Medical abortion, Nitroglycerin ., Misoprostol ,cervical ripening

ICD-10 code

XV004

ICD-10 code description

XV Pregnancy, childbirth and the puerperium ,Medical abortion

Primary outcomes

1

Description

Cervical ripening

Timepoint

Initial examination and 4 hours after receiving the drug

Method of measurement

Hegar Bogey No. 8 passes through the cervix

Secondary outcomes

1

Description

Requires mechanical dilatation

Timepoint

During curettage

Method of measurement

HegarBogey No. 8 passes through the cervix

2

Description

Possible side effects (diarrhea, chills, abdominal pain, headache, hypotension and palpitations)

Timepoint

Every 4 hours during hospitalization

Method of measurement

Questioning the patient, examination, control of vital signs

Intervention groups

1

Description

Intervention groups: Group A 85 people will receive 400 mg single dose of trinitroglycerin tablets of Dana Pharmaceutical Company vaginally.

Category

Treatment - Drugs

2

Description

Intervention group: Group B 85 people will receive 400 mg misoprostol tablets of Abu Reihan Pharmaceutical Company vaginally

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra hospital

Full name of responsible person

Dr.Fatemeh Hossein zade

Street address

Al-Zahra Hospital, Namjoo Ave., Rasht, Guilan, IRAN

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohammad Reza Naghipour

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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

Rasht University of Medical Sciences

Proportion provided by this source

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**

Rasht University of Medical Sciences

Full name of responsible person

Ghazaleh Ghorbani

Position

Resident of obstetric and gynocolog

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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

Rasht University of Medical Sciences

Full name of responsible person

Dr. fatemeh Hosseinzadeh

Position

Assistent professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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

Rasht University of Medical Sciences

Full name of responsible person

sedighe Bab Eghbal

Position

MS of Health Ejudation

Latest degree

Master

Other areas of specialty/work

Reproductive Health

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

There is still planning to share and publish

When the data will become available and for how long

The beginning of the access period is 6 months after the publication of the study results

To whom data/document is available

All interested in study

Under which criteria data/document could be used

Not yet planned for it

From where data/document is obtainable

by E mail

What processes are involved for a request to access data/document

Not yet planned for it

Comments