

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparison of successful induced abortion using misoprostol alone and misoprostol with vaginal estrogen in women candidates for first and second trimester abortions

Protocol summary

Study aim

Comparison of the effect of misoprostol alone and misoprostol with estrogen in successful induced abortion

Design

This three-phase clinical trial, with parallel groups, randomized (using the random allocation rule) is performed on 120 pregnant women.

Settings and conduct

This randomized clinical trial study is performed on 120 pregnant women, in Yas Hospital. The sampling method is a convenience method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Mother age more than 18 years, gestational age up to 28 weeks, first gravidity, first cesarean section repeat, body mass index between 25 to 35 kg/m², hemoglobin level more than 10 gr/dL. Criteria for not entering: Scar in the uterine, leiomyoma in the uterine, blood coagulation disorder, previous attempts to induce abortion in the current pregnancy, a medical disorder that prohibits abortion for example heart failure, allergy to misoprostol or estradiol, cervicitis and vaginitis, polyhydramnios and the patient withdrawal to participate in the study.

Intervention groups

In women candidates for abortion, misoprostol is prescribed according to FIGO criteria. In addition, in the intervention group, half of a vaginal estrogen ointment is administered, an hour before misoprostol prescription. Then, vaginal estrogen is administered with misoprostol if needed up to a maximum of three doses.

Main outcome variables

Successful abortion, number of misoprostol doses used, need for curettage or hysterectomy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190208042655N2**

Registration date: **2022-03-16, 1400/12/25**

Registration timing: **prospective**

Last update: **2022-03-16, 1400/12/25**

Update count: **0**

Registration date

2022-03-16, 1400/12/25

Registrant information

Name

Nafiseh Saedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2298 0727

Email address

nsaedi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-30, 1401/02/10

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of successful induced abortion using

misoprostol alone and misoprostol with vaginal estrogen in women candidates for first and second trimester abortions

Public title

Comparison of successful abortion using misoprostol alone and misoprostol with vaginal estrogen

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Mother age more than 18 years Gestational age up to 28 weeks First gravidity First cesarean section repeat Body mass index between 25 to 35 kg/m² Hemoglobin level more than 10 gr/dL

Exclusion criteria:

Scar in the uterine Leiomyoma in the uterine Blood coagulation disorder Previous attempts to induce abortion in the current pregnancy A medical disorder that prohibits abortion for example heart failure Allergy to misoprostol or estradiol Cervicitis and vaginitis Polyhydramnios The patient withdrawal to participate in the study

Age

From 18 years old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation rule: First, 60 letters A and 60 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patient. In addition, interventions A or B are determined by a lot.

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 Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, School of Medicine, Tehran Province, Tehran, Pour Sina St" to "Tehran University of Medical Sciences, School of Medicine, Tehran Province, Tehran, Pour Sina St

City

Tehran

Province

Tehran

Postal code

1598718311

Approval date

2022-02-06, 1400/11/17

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.1274

Health conditions studied

1

Description of health condition studied

The first and second trimester abortions

ICD-10 code

O03

ICD-10 code description

Spontaneous abortion

Primary outcomes

1

Description

Successful abortion

Timepoint

Once, at the end of abortion

Method of measurement

Abortion product observation (placenta and fetus residual)

Secondary outcomes

1

Description

Number of doses of misoprostol used

Timepoint

Once, at the end of abortion

Method of measurement

Counting misoprostol doses

2

Description

Need to surgery

Timepoint

Once, at the end of abortion

Method of measurement

Curettage or hysterectomy conducting

Intervention groups

1

Description

Intervention group: In women candidates for abortion, misoprostol is prescribed according to FIGO criteria. In addition, half of a vaginal estrogen ointment is administered, an hour before misoprostol prescription. Then, vaginal estrogen is administered with misoprostol if needed up to a maximum of three doses.

Category

Treatment - Drugs

2

Description

Control group: In women candidates for abortion, misoprostol is prescribed according to FIGO criteria.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas hospital

Full name of responsible person

Nafiseh Saedi

Street address

Yas hospital, Next to the sarv street , North Nejatollahi street , karim khan ave

City

Tehran

Province

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Postal code

1597856511

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+98 21 8608 9089

Email

nsaedi@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Vice-Dean of Research of Tehran University of Medical Sciences, Dr. Fotouhi

Street address

Vice-Dean of Research, Tehran University of Medical Sciences, Floor 6, Qods St., Keshavarz Blvd, Tehran, Iran

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Tehran

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1416634793

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+98 21 8163 3698

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vcr@tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Nafiseh Saedi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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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

Not applicable

Title and more details about the data/document

All data is potentially shareable after unidentified
participants

When the data will become available and for how long

After manuscript published

To whom data/document is available

No limitations

Under which criteria data/document could be used

The data is only available to the project manager, Dr.
Saedi, and any analysis must be done with her opinion.

From where data/document is obtainable

Dr. Nafiseh Saedi

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

Any request must be made in writing and accompanied
by a proposal with an ethics code under the supervision
of Dr. Nafiseh Saedi.

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

Tehran University of Medical Sciences

Full name of responsible person

Nafiseh Saedi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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