

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Comparison of the effect of misoprostol alone and misoprostol together with vaginal estrogen in preparing the cervix and induction of labor in term pregnancies

Protocol summary

Study aim

Comparison of the effect of misoprostol alone and misoprostol together with vaginal estrogen in preparing the cervix and induction of labor in term pregnancies

Design

This three-phase clinical trial, with parallel groups, randomized (using the allocation randomization rule) is performed on 200 pregnant women.

Settings and conduct

In this interventional study, 200 pregnant women are selected by convenience sampling method in Yas Hospital. This study is double-blind, the participants and the physician who evaluates the outcome are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria include term pregnancy (Gestational age >37 weeks), nulliparous woman, singleton pregnancy, and alive Fetus with the cephalic presentation, and Bishop score < 5. Exclusion criteria: Misoprostol or estrogen contraindication, women with a history the uterus surgery, and a history or family history of thromboembolism.

Intervention groups

In both groups, For termination of pregnancy, 25 micrograms of misoprostol is placed sublingual. According to the uterine contractions, every 3 to 6 hours, 25 micrograms of misoprostol is prescribed up to 4 times, or until the active phase of labor begins, or until the bishop score is 8 or higher, or until the rupture of membrane. In the intervention group, in the first and second times of misoprostol administration, an applicator of Stromarin (estrogen) cream is also placed in the posterior part of the vagina.

Main outcome variables

The interval from induction with misoprostol to the attainment of 6 cm cervical dilation, from 6 cm cervical dilation to full cervical dilation, and from full cervical dilation to active phase of labor.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230611058454N1**

Registration date: **2023-06-24, 1402/04/03**

Registration timing: **prospective**

Last update: **2023-07-25, 1402/05/03**

Update count: **1**

Registration date

2023-06-24, 1402/04/03

Registrant information

Name

Fatemeh Golshahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4216 0852

Email address

fgolshahi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-08-21, 1403/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of misoprostol alone and misoprostol together with vaginal estrogen in preparing the cervix and induction of labor in term pregnancies

Public title

The effect of misoprostol alone and misoprostol together with vaginal estrogen in induction of labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Term pregnancy (Gestational age >37 weeks)
Nulliparous woman Singleton pregnancy Alive Fetus with cephalic presentation Bishop score < 5

Exclusion criteria:

Misoprostol or estrogen contraindication Women with a history the uterus surgery Women with a history or family history of thromboembolism

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation rule: First, 100 letters A and 100 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 (misoprostol) or B (misoprotol and estrogen) are determined by a lot.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is performed double-blind, the physician evaluating outcomes and the participants do not know the type of treatment.

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

Ethics committee of Tehran University of Medical Sciences, School of Medicine, Pour Sina St., Qods Ave.

City

Tehran

Province

Tehran

Postal code

1598718311

Approval date

2023-06-11, 1402/03/21

Ethics committee reference number

اخلاق: IR.TUMS.MEDICINE.REC.1402.171

Health conditions studied

1

Description of health condition studied

Labor induction

ICD-10 code

O61.0

ICD-10 code description

Failed medical induction of labor

Primary outcomes

1

Description

Interval from induction with misoprostol to the attainment of 6 cm cervical dilation

Timepoint

Once, after delivery

Method of measurement

Information entered in the patient's delivery record

2

Description

Interval from 6 cm cervical dilation to full cervical dilation

Timepoint

Once, after delivery

Method of measurement

Information entered in the patient's delivery record

3

Description

Interval from full cervical dilation to active phase of labor

Timepoint

Once, after delivery

Method of measurement

Information entered in the patient's delivery record

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For termination of pregnancy, 25 micrograms of misoprostol is placed sublingual. According to the uterine contractions, every 3 to 6 hours, 25 micrograms of misoprostol is prescribed up to 4 times, or until the active phase of labor begins, or until the bishop score is 8 or higher, or until the rupture of membrane. In the first and second times of misoprostol administration, an applicator of Stromarin (estrogen) cream is also placed in the posterior part of the vagina.

Category

Treatment - Drugs

2

Description

Control group: For termination of pregnancy, 25 micrograms of misoprostol is placed sublingual. According to the uterine contractions, every 3 to 6 hours, 25 micrograms of misoprostol is prescribed up to 4 times, or until the active phase of labor begins, or until the bishop score is 8 or higher, or until the rupture of membrane.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas hospital

Full name of responsible person

Fatemeh Golshani

Street address

Yas hospital, Nejatollahi St., Karimkhan Blvd.

City

Tehran

Province

Tehran

Postal code

1597856511

Phone

+98 21 8608 9089

Email

Fgolshahi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

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

City

Tehran

Province

Tehran

Postal code

1416634793

Phone

+98 21 6381 9836

Email

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

Fatemeh Golshahi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Yas hospital, North Nejatollahi St., Karimkhanzand Blvd.

City

Tehran

Province

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Postal code

1598718311

Phone

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Fax

Email

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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

No - There is not 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

No - There is not 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 the manuscript is 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. Golshahi, and any analysis must be done with her opinion.

From where data/document is obtainable

Dr. Golshahi.

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

Any request must be sent by e-mail with its proposal to Dr. Golshahi.

Comments