

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Comparison of the effect of misoprostol and misoprostol with Foley cervical catheter for termination of pregnancy in women undergoing previous cesarean section in the second trimester of pregnancy

#### Protocol summary

##### Study aim

Comparison of the effect of misoprostol and misoprostol with Foley cervical catheter for termination of pregnancy in women undergoing previous cesarean section in the second trimester of pregnancy

##### Design

A controlled clinical trial, with parallel, randomized groups, on 82 patients. Excel software generated random numbers were used for randomization.

##### Settings and conduct

This study will be performed in the maternity ward of Umm Al-Banin and Ghaem hospitals in Mashhad. No blinding was performed in this study.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: history of previous cesarean section, gestational age of 15-28 weeks, intact membranes, no vaginal bleeding, desire to enter the study. Non-inclusion criteria: Hypersensitivity to prostaglandins, cervical stenosis, history of cesarean section more than three times

##### Intervention groups

Control group: receiving sublingual misoprostol.

Intervention group: Receiving sublingual misoprostol with Foley catheter number 16

##### Main outcome variables

Duration from the beginning of the intervention to vaginal delivery, the rate of vaginal delivery in less than 24 hours, the number of misoprostol doses

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200608047685N3**

Registration date: **2022-04-30, 1401/02/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-04-30, 1401/02/10**

Update count: **0**

##### Registration date

2022-04-30, 1401/02/10

##### Registrant information

###### Name

Elaheh Mansouri

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3273 5002

###### Email address

mansourie94150@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2022-01-05, 1400/10/15

##### Expected recruitment end date

2022-08-06, 1401/05/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of misoprostol and misoprostol with Foley cervical catheter for termination of pregnancy in women undergoing previous cesarean section in the second trimester of pregnancy

##### Public title

Comparison of the effect of misoprostol alone and misoprostol with Foley catheter in termination of

pregnancy in the second trimester

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

History of previous cesarean section Gestational age 15-28 weeks Intact membrane No vaginal bleeding Willingness to enter the study

**Exclusion criteria:**

Allergy to prostaglandins Cervical Stenosis A history of more than three cesarean sections

**Age**

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **82**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Excel software will be used to assign people to the control and intervention group. In this way, random codes prepared by Excel software are written as A / B codes on separate sheets. Each sheet is placed separately in an envelope so that the code inside it is not recognizable. With the referral of each eligible patient and after obtaining informed consent, an envelope is taken out and the patient is treated according to the code inside the envelope (code A for the control group and code B for the intervention group).

**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 Mashhad University of Medical Sciences

**Street address**

Ghoreishi building; Daneshgah Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

1234567890

**Approval date**

2021-12-28, 1400/10/07

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1400.655

**Health conditions studied****1****Description of health condition studied**

Disposal of vaginal products after previous cesarean section in the second trimester of pregnancy

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Duration from the beginning of the intervention to vaginal delivery

**Timepoint**

During the intervention

**Method of measurement**

By the hour and with the help of vaginal examination by hand

**Secondary outcomes****1****Description**

Vaginal delivery in less than 24 hours

**Timepoint**

From the beginning of the intervention until 24 hours later

**Method of measurement**

Per hour and using a questionnaire

**2****Description**

Number of doses of misoprostol

**Timepoint**

During the intervention

**Method of measurement**

Questionnaire

**Intervention groups****1****Description**

Intervention group: cases with fetus with FHR receive 200 micrograms of sublingual misoprostol every three hours (maximum 5 doses) until the onset of effective uterine contractions (at least 3 contractions in 10 minutes) or expulsion of pregnancy products and cases with IUFD receive half of this dose. If pregnancy products

are not excreted within 24 hours of the intervention, the same protocol will be repeated for the patient. In addition to receiving sublingual misoprostol, the research units in this group will also receive Foley catheter number 16.

**Category**

Treatment - Drugs

**2****Description**

cases with fetus with FHR receive 200 micrograms of sublingual misoprostol every three hours (maximum 5 doses) until the onset of effective uterine contractions (at least 3 contractions in 10 minutes) or expulsion of pregnancy products and cases with IUFD receive half of this dose. If pregnancy products are not excreted within 24 hours of the intervention, the same protocol will be repeated for the patient.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Ghaem Hospital

**Full name of responsible person**

Masoumeh Mirtaimouri

**Street address**

Ghaem Hospital, AhmadAbad Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

99199-91766

**Phone**

+98 51 3840 0001

**Fax**

+98 51 3845 3239

**Email**

b.ghaem@mums.ac.ir

**Web page address**

<https://quaem.mums.ac.ir/>

**2****Recruitment center****Name of recruitment center**

Ommolbanin Hospital

**Full name of responsible person**

Masoumeh Mirtaimouri

**Street address**

At the corner of Ayatollah Behjat .16, Zarrineh intersection

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9144734767

**Phone**

+98 51 3223 1061

**Fax****Email**

oah@mums.ac.ir

**Web page address**

<https://woman.mums.ac.ir/>

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Majid Ghayor Mobarhan

**Street address**

Ghoraish Street, Doctora crossroad

**City**

Mashhad

**Province**

South Khorasan

**Postal code**

9138813944

**Phone**

+98 51 3841 1538

**Email**

GhayourM@mums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Masoumeh Mirtaimouri

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

At the corner of Ayatollah Behjat .16, Zarrineh intersection

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

1234567890

**Phone**

+98 915 310 6875

**Email**

Mirtaimourim@mums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Masoumeh Mirteimori

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

At the corner of Ayatollah Behjat 16, Zarrineh Crossroads

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

1234567890

**Phone**

+98 915 310 6875

**Email**

Mirteimorim@mums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Maryam Abbasi

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

At the corner of Ayatollah Behjat 16, Zarrineh Crossroads

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

1234567890

**Phone**

+98 915 519 1068

**Email**

Abbasimaryam987@gmail.com

**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**

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

**Statistical Analysis Plan**

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

**Informed Consent Form**

Undecided - It is not yet known if there will be 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**

Not applicable