

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Comparison Between Evening Primrose And Misoprostol On The Cervical Ripening And Dilatation Before Gynecologic Surgeries

#### Protocol summary

##### Study aim

Comparison between effect of vaginal Primrose with Misoprostol on the cervical ripening and dilatation in non-menopausal women without a history of NVD, or menopausal women that are candidates for gynecologic surgeries

##### Design

The study design based on a randomized double-blind controlled trial ,accomplish with 42 subjects(20-75 years).

##### Settings and conduct

The study pupolation are at least 42 patients (20-75) that refer to Shohadaye Tajrish hospital Gynecology clinic and are candidates surgeries. By simple randomization method ,21 patients receive 2 soft gels(each 500 mg) of Primrose ,and 21 patients receive 2 tablets (each 200 micro-gram) of Misoprostol.Druges apply to the posterior vaginal fornix,2-4 hours before the surgery. This study evaluate the total dilatation time,the first Hegar size used to apply force,blood loss,complications drugs side effects .

##### Participants/Inclusion and exclusion criteria

Study population are 20-75 years old women that are candidates for hysteroscopic surgeries ,D&C,laparoscopic hysterectomy ,and any others need uterine manipulator insertion. The inclusion criteria Non-menopausal women without a history of NVD Menopausal women The exclusion criteria Ahistory of NVD Contraindications for the use of Primrose or Misoprostol Structural anomalies of cervix(incometency ,Mullerian anomaly) history of cervical cone biopsy

##### Intervention groups

Number of 21 patients(at least) of 20-75 years old menopausal patients ,or premenopausal women without a history of NVD. vaginal administration of 2 Primrose 500mg capsules 2hours before the surgery. Control group: Number of 21 patients with the same characters : vaginal administration of 2 Misoprostol 200 mic tablets,2 hours before the surgery.

#### Main outcome variables

Total dilatation time the first Hegar size usde to apply force Blood loss Drugs side effects Surgical complications

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190210042673N1**

Registration date: **2019-04-20, 1398/01/31**

Registration timing: **prospective**

Last update: **2019-04-20, 1398/01/31**

Update count: **0**

##### Registration date

2019-04-20, 1398/01/31

##### Registrant information

##### Name

Behnaz Nouri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7747 1287

##### Email address

nouri@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-21, 1398/02/01

##### Expected recruitment end date

2019-07-23, 1398/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison Between Evening Primrose And Misoprostol On The Cervical Ripening And Dilatation Before Gynecologic Surgeries

**Public title**  
"Effect of Primrose on non-pregnant cervical ripening  
""effect of Misoprostol on non-pregnant cervical ripening  
"

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Non-menopause women without history of previous normal vaginal delivery Menopause women  
**Exclusion criteria:**  
Previous Normal Vaginal Delivery Structural Cervical Anomaly such as cervical incompetency Mullerian Anomalies Previous Cervical Conization Contraindications of Misoprostol and Primrose

**Age**  
From **20 years** old to **75 years** old

**Gender**  
Female

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**  
Target sample size: **42**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Simple randomization- Computer-generated random numbers select between 0-1 according to total sample size (42). Numbers which are less than 0.5 assign of the intervention group and those are greater than 0.5 assign of the control group.

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Drugs administrate by resident based on randomization patient's numbers without awareness of both participants and study staff

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

##### Street address

Shohadaye Tajrish Hospital., Shahrday street., Quds Square

##### City

Tehran

##### Province

Tehran

##### Postal code

1745953311

#### Approval date

2019-02-20, 1397/12/01

#### Ethics committee reference number

IR.SBMU.RETECH.REC.1397.1293

## Health conditions studied

### 1

#### Description of health condition studied

Comparison Between Evening Primrose And Misoprostol On The Cervical Ripening And Dilatation Before Gynecologic Surgeries

#### ICD-10 code

N93.9

#### ICD-10 code description

Abnormal uterine and vaginal bleeding, unspecified

## Primary outcomes

### 1

#### Description

Total cervical dilatation time

#### Timepoint

From the first Hegar to the tenth Hegar

#### Method of measurement

Second

### 2

#### Description

The first Hegar size used to apply force

#### Timepoint

During surgery

#### Method of measurement

Hegar size number

### 3

#### Description

Blood loss

#### Timepoint

Estimated blood loss during surgery

#### Method of measurement

mililiter

## Secondary outcomes

### 1

#### Description

Drugs side effects

#### Timepoint

After administration, 6hand24h

#### Method of measurement

Observation, Questionnaire

### 2

#### Description

Complications of surgery

#### Timepoint

During surgry

#### Method of measurement

Check list

## Intervention groups

### 1

#### Description

Intervention group: Non-pregnant women without history of normal vaginal delivery,or menopause women, that need cervical dilation before the surgery.Vaginal administration of 2Primrose capsules 500mg ,2 hours before surgery.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Non -pregnant women without history of normal vaginal delivery ,or menopause women ,that need cervical dilation before the surgery with vaginal administration 2 Misoprostol tablets 200 mic,2 hours before the surgery.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shohadaye Tajrish Hospital

##### Full name of responsible person

Behnaz Nouri

##### Street address

Shohadaye Tajrish Hospital., Shahrdary Street., Quds Square

##### City

Tehran

##### Province

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#### Postal code

1989934148

#### Phone

+98 21 2271 8000

#### Email

b.nouri1376@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Dr.Babak Shokri

##### Street address

Shahid Beheshti medical science universityAddress:  
Tehran Province, Tehran, District 1, Daneshjou  
Boulevard,

##### City

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##### Province

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##### Postal code

1983969411

##### Phone

+98 21 2990 2233

##### Email

pgrc@sbm.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahid Beheshti University of Medical Sciences

#### Proportion provided by this source

20

#### 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Behnaz Nouri

##### Position

Assist.Prof GYN

##### Latest degree

Specialist

##### Other areas of specialty/work

Gynecology and Obstetrics

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Shohadaye Tajrish Hspital,Shahrdary Street,Qods SQ

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

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**Latest degree**

Specialist

**Other areas of specialty/work**

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

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Behnaz Nouri

**Position**

Assist.Prof GYN

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

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**City**

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**Province**

Tehran

**Postal code**

1989934148

**Phone**

+98 25719

**Email**

b.nouri1376@gmail.com

**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**

Total cervical dilation time ,size of the first Hegar used to apply force/Blood loss/drugs side effects/complications/type of surgery/menopausal status/age/Gravidity/pariaty/BMI

**When the data will become available and for how long**

5MONTHES

**To whom data/document is available**

Researchers /OB&GYN

**Under which criteria data/document could be used**

FOR RESEARCH AND Clinical utilization

**From where data/document is obtainable**

DR.Behnaz Nouri

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

Contact with Dr Behnaz Nouri

**Comments**