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 of2 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 0-1acorrding 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., Shahrdary 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, Questionaire

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
Tehran
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
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 2990 2233
Email
pgrc@sbmu.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

Street address
Shohadaye Tajrish Hspital,Shahrdary Street,Qods SQ
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 2274 9201
Email
b.nouri1376@gmail.com

Person responsible for scientific 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
Street address
Shahid Beheshti university,Yaman street ,Daneshjo BL
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 29902233
Email
pr.office@mail.sbu.ac.ir
Web page address
https://www.sbu.ac.ir

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
Shohadaye Tajrish Hospital,Shahrdari street,Qods SQ
City
Tehran
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