

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison of effects of vaginal misoprostol tablet with vaginal evening primrose capsule on ripening of the cervix in nulliparous women

Protocol summary

Study aim

Determine and compare the effect of vaginal misoprostol tablet with vaginal evening primrose capsule on ripening of the cervix Determine and compare the effect of vaginal misoprostol tablet with vaginal evening primrose capsule on bishop score before and after intervention

Design

The aim of this study is to determine and compare the effect of vaginal misoprostol tablet with vaginal evening primrose capsule on ripening of the cervix as a single-blind randomized clinical trial on 90 primiparous women with gestational age of 40 weeks (45 patients in the misoprostol group and 45 in the Gorgan group) which will have the following conditions: First pregnancy, gestational age 40 weeks based on the first day of the last menstruation or first trimester ultrasound, Bisap score less than 4, normal biophysical and non-stress test. Mothers, who have potential drug-related complications and problems such as Lack of Fetal Movement and bleeding, will be excluded. Study phase: not applicable. The simple random method is used.

Settings and conduct

The misoprostol group will be given the vaginal misoprostol tablet that will be supervised and ordered by a gynecologist in hospital based on a 25-microgram (one-eighth vaginal tablet 200 micrograms) dose from the 40th week of pregnancy. The evening primrose group will use a 1000 mg capsule of evening primrose vaginal from 40 weeks of gestation daily for one week, which will be placed by the researcher in their cervix, and each day be referred to a researcher in the clinic to place the capsule. The training will be given on how to count the movements of the fetus and the symptoms of the onset of labor. the daily registration form will be provided to the units. Both groups will be followed by researcher from time of admission and the results of the examinations will be recorded in the form. Maternity ward of Pasteur Hospital and selected clinic affiliated to Bam University of Medical Sciences

Participants/Inclusion and exclusion criteria

First pregnancy, gestational age 40 weeks based on the first day of the last menstruation or first trimester ultrasound, Bisap score less than 4, normal biophysical and non-stress test. Mothers, who have potential drug-related complications and problems such as Lack of Fetal Movement and bleeding, will be excluded.

Intervention groups

The misoprostol group will get the vaginal misoprostol tablet which be supervised and ordered by a gynecologist in hospital based on a 25-microgram (one eighth vaginal tablet 200 micrograms) dose from the 40th week of pregnancy The evening primrose group, 1000 mg capsule of evening primrose Vaginal, from the 40th week of gestation, is given one day per day for one week and Placed by the researcher in their cervix.

Main outcome variables

Ripening of the cervix

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180101038176N1**

Registration date: **2018-03-03, 1396/12/12**

Registration timing: **prospective**

Last update: **2018-03-03, 1396/12/12**

Update count: **0**

Registration date

2018-03-03, 1396/12/12

Registrant information

Name

Narges Mirzadeh

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-12, 1396/12/21

Expected recruitment end date

2018-07-01, 1397/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effects of vaginal misoprostol tablet with vaginal evening primrose capsule on ripening of the cervix in nulliparous women

Public title

Comparison of effects of misoprostol with evening primrose on ripening of the cervix in nulliparous women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18-35 years old First pregnancy Singleton pregnancy Presentation of fetal cephalic Live fetal Gestational age 40 weeks based on the first day of the last menstruation and first trimester Medical ultrasound Natural pattern of fetal heartbeat No uterine contractions Bishop score less than 4 Healthy amniotic bag Mother's height is more than 150 cm BMI less than 30 Not having drug abuse Natural biophysical profiling test at the time of starting the study Having an ultrasound for pair grading (zero and one Grade) Estimated fetal weighing 2500-4000 gr based on manual examination of the abdomen or ultrasound Low risk pregnancy (Not suffering from known internal and surgical diseases and complications of pregnancy such as previa, abruption, preeclampsia, and the absence of known fetal problems) No vaginal examination a 24 hours before starting the study Avoid doing enema, sexual intercourse, laxative, herbal medicines including castor oil and homeopathic remedies, chemotherapy, breast stimulation and traditional methods of initiating Birth pain 24 hours before the start of study until the end

Exclusion criteria:

Any problems that require emergency action, such as not moving the fetus, mother's bleeding Get any herbal medicine during the study period Intercourse during the study possible side effects of the drug Cancellation of participation in the study at each stage

Age

From 18 years old to 35 years old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

The study units is divided into two groups by simple random method in two groups: misoprostol and evening primrose. a 90- pocket box is placed , each of the pockets is assigned to one of the two groups of misoprostol and evening primrose by random number table. The first person removes the pocket number 1, and next members will remove the pockets in their order numbers and assign them to the groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Eligible participants are kept blind to being assigned to dedicate study groups. It is explained to those who are in one of the two groups of misoprostol and evening primrose, but they do not know which group they are.

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

Shahid Beheshti University of Medical Sciences, Velenjak St., Shahid Chamran Highway, Tehran, Iran

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tehran

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Postal code

1985717443

Approval date

2017-10-09, 1396/07/17

Ethics committee reference number

IR.SBMU.PHNM.1396.851

Health conditions studied

1

Description of health condition studied

ripening of the cervix
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

Ripening of the cervix

Timepoint

since the onset of intervention and labor

Method of measurement

Bishop's Scoreboard

Secondary outcomes

empty

Intervention groups

1

Description

The evening primrose group, 1000 mg capsule of evening primrose Vaginal, from the 40th week of gestation, is given one day per day for one week and Placed by the researcher in their cervix.

Category

Treatment - Drugs

2

Description

Control group:The misoprostol group will be given the vaginal misoprostol tablet that will be supervised and ordered by a gynecologist in hospital based on a 25-microgram (one-eighth vaginal tablet 200 micrograms) dose from the 40th week of pregnancy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Maternity ward of Pasteur hospital and selected clinic affiliated to Bam university of medical scien

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Narges Mirzade

Position

Midwifery Master Student

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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

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