

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Investigation the Effect of vaginal Evening Primrose capsule on cervix preparation in nulliparous Women

Protocol summary

Study aim

Determining the effect of vaginal Evening Primrose capsule on Bishop score in nulliparous women.

Design

Clinical trial with a control group, community-based and pragmatic, with parallel groups, double-blind, randomized

Settings and conduct

Study population contains all the pregnant women who would refer to the health centers of Rafsanjan. So 86 women, with regard to the inclusion and exclusion criteria, would be enrolled in the study using convenient method and then would be allocated into two groups of control and intervention using simple randomization. Training about the method of placing the Primrose capsule and placebo in the posterior fornix would be conducted using a replica in the intervention and control groups, and they would be advised to use one Primrose capsule or placebo every night before sleeping from the 38th week of pregnancy until the birth symptoms occur. The participants and the individuals in charge of distributing the capsules would not be aware of the control and intervention groups' allocation. Information about the Bishop score would be extracted from the delivery file of women and related forms would be completed.

Participants/Inclusion and exclusion criteria

The inclusion criteria: willingness to participate in the study, willingness to have vaginal delivery and being 18-35 years old The exclusion criteria: not taking two consecutive capsules of Evening Primrose.

Intervention groups

Intervention group: Daily vaginal use of 1 capsule of prime Rose every night before bedtime from the 38th week of pregnancy until the time of delivery Control group: Using placebo in the same manner as the intervention group

Main outcome variables

Bishop score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160308026971N4**

Registration date: **2018-06-10, 1397/03/20**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-10, 1397/03/20**

Update count: **0**

Registration date

2018-06-10, 1397/03/20

Registrant information

Name

Marzeyeh Loripoor

Name of organization / entity

Rafsanjan University Medical Science

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Rafsanjan University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the Effect of vaginal Evening Primrose capsule on cervix preparation in nulliparous Women

Public title

Investigation the Effect of vaginal Evening Primrose capsule on cervical preparation for childbirth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclination to participate in the study
Tendency to normal delivery
Selection of Niknafs hospital for delivery
Mother's age is 18-35 years
Gestational age 38 weeks based on first trimester Ultrasonography or reliable IMP
Single fetus with cephalic presentation
The basis of the results of the last ultrasound
Nulliparity the integrity of the embryonic membranes

Exclusion criteria:

Non-use of two successive capsules of Primrose
Primrose capsule susceptibility
Emergency intervention for maternal or embryonic reasons
Unwillingness of the research unit to continue cooperation
Vaginal bleeding
Presence of contraindications for use of Evening Primrose capsule (diseases associated with disorders Hemorrhagic agents, anticoagulant drugs, Patients with history of psychiatric disorders in the phenothiazine category, and epilepsy patients)
History of known chronic disease
Pregnancy complications such as Hydromenosis, Oligohydroamenia, Pre-eclampsia, Eclampsia

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of random allocation in this study is simple randomization and its tool is a random number table. At first, the researcher referred to the public health centers of Rafsanjan (Nos. 1, 4, and 5). She chose all the eligible pregnant women in the apple system and, after telephone conversation with each of the women, explained the research, if Their willingness to participate in the study, each of them assigned a number, and then the random numbers table is used to select the members of the intervention and control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the research units and the clinical caregiver are unaware of any sample in which of the control and

intervention groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rafsanjan University Medical Science

Street address

Imam Ali street, cenral department of Rafsanjan University Medical Science

City

Rafsanjan

Province

Kerman

Postal code

7717932777

Approval date

2017-08-05, 1396/05/14

Ethics committee reference number

IR.RUMS.REC.1396.89

Health conditions studied

1

Description of health condition studied

Bishop Score

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Bishop score

Timepoint

After intervention

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

The drug used in this study is soft Barich EPO capsule or Evening Primrose Oil capsule produced by Barich Essence Company. Each soft capsule contains 1000 mg of Evening Primrose Oil and 140-70 mg gamma linolenic acid (GLA). Each study unit in the intervention group is given 21 units. From the beginning of the 38th week of gestation until the day of delivery, one capsule of Evening Primrose Oil embeds in the posterior fornix.

Category

Treatment - Drugs

2

Description

Twenty-one placebos are presented to the control group in the same way as Evening Primrose Oil capsule, manufactured by the Barich Essence pharmaceutical company, From the beginning of the 38th week of gestation until the day of delivery, one placebo of Evening Primrose capsule embeds in the posterior fornix.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health center No.1

Full name of responsible person

Motahare Najafi

Street address

Health Center No. 1, Imam Khomeini Street, Ghods Square

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2

Recruitment center

Name of recruitment center

Health center No.4

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Health center No.5

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

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

Rafsanjan 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

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Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is not more information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available