Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

Comparative study of the effect of vaginal consumption of primrose oil with vaginal misoprostol on cervical preparation in nulliparous women with prolonged pregnancy

Protocol summary

Study aim
Comparative study of the effect of vaginal consumption of primrose oil with vaginal misoprostol on cervical preparation in nulliparous women with prolonged pregnancy

Design
Clinical trial without control group with parallel, randomized, phase 3 groups on 110 patients A random number table was used for randomization.

Settings and conduct
This study is performed in Al-Zahra Hospital in Isfahan. Patients are randomly divided into two groups. Patients are treated with misoprostol or primrose oil according to their group. The rate of effusion and uterine dilatation in pregnant women will be measured and compared every 10 minutes.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Duration of pregnancy 40 weeks and more, Primiparous women, Single delivery, Satisfaction to participate in the study Exclusion criteria: The patient refuses to continue attending the study for various reasons, Patient discharge with personal consent

Intervention groups
Intervention group 1: Patients in this group are treated with a quarter of 500 mg misoprostol vaginal tablets. The rate of Effacement and uterine dilatation in pregnant women is measured every 10 minutes by a physical exams. Intervention group 2: Patients in this group are treated with 1000 mg vaginal capsule of primrose oil. The rate of Effacement and uterine dilatation in pregnant women is measured every 10 minutes by a physical exams.

Main outcome variables
Uterine dilatation rate, Effacement percentage

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200217046523N14**
Registration date: **2021-04-20, 1400/01/31**
Registration timing: **prospective**

Last update: **2021-04-20, 1400/01/31**
Update count: **0**

Registration date
2021-04-20, 1400/01/31

Registrant information

Name
Aryan Rafiee Zadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 83 3837 1582

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rafieezadeh.a@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-29, 1400/02/09

Expected recruitment end date
2021-05-30, 1400/03/09

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of the effect of vaginal consumption of primrose oil with vaginal misoprostol on cervical preparation in nulliparous women with prolonged pregnancy

Public title
The effect of vaginal consumption of evening primrose oil on cervical preparation

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Duration of pregnancy 40 weeks and more Primiparous women Single delivery Satisfaction to participate in the study Age between 18- 35 years

Exclusion criteria:
The patient refuses to continue attending the study for various reasons Patient discharge with personal consent

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

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Not randomized

Randomization description

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 IsfahanUniversity of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave., Isfahan

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2020-09-25, 1399/07/04

Ethics committee reference number
IR.MUI.MED.REC.1399.530

Health conditions studied

1

Description of health condition studied
Prolonged first stage (of labor)

ICD-10 code
O63.0

ICD-10 code description
Prolonged first stage (of labor)

Primary outcomes

1

Description
Uterine dilatation rate

Timepoint
Every 10 minutes

Method of measurement
Physical examination

2

Description
Effacement percentage

Timepoint
Every 10 minutes

Method of measurement
Physical examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients in this group are treated with a quarter of 500 mg misoprostol vaginal tablets. The rate of Effacement and uterine dilatation in pregnant women is measured every 10 minutes by a physical exams.

Category
Treatment - Drugs

2

Description
Intervention group 2: Patients in this group are treated with 1000 mg vaginal capsule of primrose oil. The rate of Effacement and uterine dilatation in pregnant women is measured every 10 minutes by a physical exams.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Al-Zahra hospital

Full name of responsible person
Azar Danesh Shahraki

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No. 22, Roshd Ave., Daneshgah Blvd., Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Shaghayegh Haghjoo

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Isfahan University of Medical Sciences, Hezar Jarib Ave,. Daneshgah Blvd, Isfahan

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Web page address

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Azar Danesh Shahraki

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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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
All data can be shared after people have requested.
When the data will become available and for how long
Six months after publishing the results.
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
Scientific uses
From where data/document is obtainable
Isfahan University of Medical Sciences website
What processes are involved for a request to access data/document
Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.
Comments