

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)

Phone

+98 83 3837 1582

Email address

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 Isfahan University of Medical Sciences

Street address

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

City

Isfahan

Province

Isfahan

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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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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Person responsible for updating data

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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