

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### A comparative study of the effect of evening primrose oil capsule and misoprostol on cervical ripening in pregnant women candidate for termination of pregnancy

#### Protocol summary

##### Study aim

A comparative study of the effect of evening primrose oil capsule and misoprostol on cervical ripening in pregnant women candidate for termination of pregnancy

##### Design

This study is a one-blinded clinical trial. The study population will be included all women candidates for termination of pregnancy referred to Imam Reza Hospital of Kermanshah. Sixty eligible pregnant women will be selected conveniently and randomly assigned to intervention and control groups.

##### Settings and conduct

The study, which will be conducted at Imam Reza Hospital of Kermanshah, is one-blind one as participants are unaware of the allocation of study groups. After intervention and suppository, the monitor is checked continuously for 1 hour and after 3 hours fetal ECG test is recorded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Healthy amniotic sac; No substance abuse; Mothers with height >150 cm Exclusion criteria: Known fetal problems

##### Intervention groups

The intervention group will receive two 500 mg gel capsules into the vaginal posterior fornix. 6-8 hours later, if there is an increase in the Bishop score, the induction is performed and if no change is observed, the intervention protocol with primrose oil will be repeated. The control group will also receive a misoprostol 25 microgram suppository every 6 hours when the mother's Bishop score is less than 6.

##### Main outcome variables

Ripening Of Cervix

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130812014333N129**

Registration date: **2019-10-28, 1398/08/06**

Registration timing: **prospective**

Last update: **2019-10-28, 1398/08/06**

Update count: **0**

##### Registration date

2019-10-28, 1398/08/06

##### Registrant information

##### Name

Feizollah Foroughi

##### Name of organization / entity

kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1821 4653

##### Email address

froughi@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-11-06, 1398/08/15

##### Expected recruitment end date

2020-06-04, 1399/03/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparative study of the effect of evening primrose oil capsule and misoprostol on cervical ripening in pregnant women candidate for termination of pregnancy

#### Public title

Comparison of the effect of evening primrose oil capsule and misoprostol on cervical ripening

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Gestational age from (37 completed weeks) to (40 weeks + 6 days) based on the beginning of the last menstrual period and first trimester ultrasound Natural pattern of fetal heart rate Healthy amniotic sac No substance abuse mothers with height >150 cm

##### Exclusion criteria:

Known fetal problems

#### Age

No age limit

#### Gender

Female

#### Phase

2-3

#### Groups that have been masked

- Participant

#### Sample size

Target sample size: 60

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomly Individually by random number table via code receipt

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

In this study, patients were kept blind to study groups, drug dosage, and drug manufacturer

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

###### Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

###### City

Kermanshah

###### Province

Kermanshah

###### Postal code

6715847141

###### Approval date

2019-05-08, 1398/02/18

###### Ethics committee reference number

ir.kums.rec.1398.709

### Health conditions studied

#### 1

##### Description of health condition studied

Ripening Of Cervix

##### ICD-10 code

O75.9

##### ICD-10 code description

Complication of labor and delivery, unspecified

### Primary outcomes

#### 1

##### Description

Ripening Of Cervix

##### Timepoint

One and three hours after the end of the intervention

##### Method of measurement

Using Monitoring

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

The intervention group will receive two 500 mg gel capsules into the vaginal posterior fornix. 6-8 hours later, if there is an increase in the Bishop score, the induction is performed and if no change is observed, the intervention protocol with primrose oil will be repeated.

##### Category

Treatment - Drugs

#### 2

##### Description

The control group will also receive a misoprostol 25 microgram suppository every 6 hours when the mother's Bishop score is less than 6.

##### Category

Treatment - Drugs

### Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Mona Zeynolabedin

**Street address**

Imam Reza Hospital, Parastar Boulevard

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3427 6306

**Email**

monazblue@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Farid Najafi

**Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3836 0014

**Email**

fnajafi@kums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Mona Zeynolabedin

**Position**

Resident of Obstetrics and Gynecology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Imam Reza Hospital, Parastar Boulevard

**City**

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**Province**

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**Postal code**

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**Phone**

+98 83 3427 6306

**Email**

monazblue@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Nasrin Jalilian

**Position**

Member of Kermanshah University of Medical Sciences

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

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**Email**

njalilian@kums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Mona Zeynolabedin

**Position**

Resident of Obstetrics and Gynecology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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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**

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

make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The main outcomes of the study will be shared.

**When the data will become available and for how long**

6 month

**To whom data/document is available**

If requested, results will be made available to other academic researchers

**Under which criteria data/document could be used**

Collected data is confidential and will not be shared with anyone else

**From where data/document is obtainable**

To receive the documentation, email send for update manager

**What processes are involved for a request to access data/document**

In a 15-day period, the documents will be sent e-mail

**Comments**