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'sBishop 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

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Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
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Iran (Islamic Republic of)
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fforoughi@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'sBishop 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

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6715847141

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+98 83 3836 0014

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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

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Imam Reza Hospital, Parastar Boulevard

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
Member of Kermanshah University of Medical Sciences

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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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

Gynecology and Obstetrics

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Postal code

6715847141

Phone

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Email

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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