Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Comparing effect of oral and vaginal evening primrose oil on cervical ripening in pregnant women

Protocol summary

Study aim

Comparing effect of oral and vaginal evening primrose oil on cervical ripening in pregnant women

Design

The clinical trial consists of 3 groups of 40 people, with control group with parallel groups and random allocation as block.

Settings and conduct

Women visited by the maternity ward of Hazrat-e-Valiasr hospital with criteria to enter the study, will be tested by bishop score. if they have a Bishop score less than 4 or equal to it, they will be considered as intervention group. Then the intervention group will be divided into two groups. The first group will receive the medication for one week every 12 hours and then, once a day, until the onset of labor pains orally and the second one will receive the capsule vaginally. The control group will receive no intervention. Eventually after the intervention, once again the Bishop score will be tested and compared.

Participants/Inclusion and exclusion criteria

Entry requirements: 1- Low-risk primiparous women 2- Bishop score less than or equal to 4 at the time of drug administration 3-Cephalic presentation of the fetus 4. Single pregnancy 5. Gestational age 39 weeks 6. Normal test of fetal health assessment within the last 48 hours Exclusion criteria: A history of uterine surgery

Intervention groups

In intervention groups from 39 week of pregnancy, both groups will take the evening primrose oil capsules every 12 hours for one week, and after that once a day, until the onset of labor pains. One of these groups will take the evening primrose oil capsules orally and the other group will take it vaginally. The control group will not receive any intervention.

Main outcome variables

Prepare cervix; improve labor; reduce duration of labor.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200118046180N1**
Registration date: **2020-07-23, 1399/05/02**
Registration timing: **retrospective**

Last update: **2020-07-23, 1399/05/02**
Update count: **0**

Registration date

2020-07-23, 1399/05/02

Registrant information

Name

Parisa Heydari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3242 6594

Email address

parisa.heydary@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-04, 1398/11/15

Expected recruitment end date

2020-06-19, 1399/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of oral and vaginal evening primrose oil on cervical ripening in pregnant women

Public title
effect of evening primrose oil on cervical ripening
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Primiparous and low-risk pregnant women Gestational age 39 weeks Cephalic presentation bishop score of 4 or less Single pregnancy
Exclusion criteria:
A history of uterine surgery
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Random allocation will be conducted in the form of Block Randomization. The first intervention group will be marked with the letter A, the second intervention group will be marked with the letter B, and the control group will be marked with the letter C. In the next step, six similar cards will be prepared and on each card, different rows of ABC letters (ABC, ACB, BCA,...) will be written, Each time a card is randomly selected, and after noting the order, it will be added again to the other cards. This process will continue until the sample size is completed.
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 Tehran University of Medical Sciences
Street address
No.15, Shahid Tafakori Ave. Shohada Town
City
Bafq
Province
Yazd
Postal code
8971717479
Approval date
2019-10-15, 1398/07/23
Ethics committee reference number
IR.TUMS.FNM.REC.1398.134

Health conditions studied

1

Description of health condition studied
Cervical ripening
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Cervical Preparation
Timepoint
Before the intervention and at the time of hospitalization for delivery
Method of measurement
Bishop's score measurement

Secondary outcomes

1

Description
Duration of hospitalization to delivery
Timepoint
Duration of hospitalization to delivery
Method of measurement
questionnaire

2

Description
Newborn Agar score
Timepoint
The first minute and Fifth minutes after birth
Method of measurement
questionnaire

3

Description
type of delivery
Timepoint
End of intervention
Method of measurement
questionnaire

4

Description

Need to induction

Timepoint

hospitalization until delivery

Method of measurement

questionnaire

Intervention groups

1

Description

First intervention group: In the first group, a bottle containing 1000 mg of evening primrose oil capsule made by Barij Essence Company will be given to mothers to use vaginally every week for 12 weeks from 39 weeks of pregnancy and then until the onset of labor pains once a day. If labor pains do not start or there are few contractions at the time of hospitalization, 10 oxytocin units will be induced.

Category

Treatment - Drugs

2

Description

second intervention group: In the second group, a bottle containing 1000 mg of evening primrose oil capsule made by Barij Essence Company will be given to mothers to use orally every week for 12 weeks from 39 weeks of pregnancy and then until the onset of labor pains once a day. If labor pains do not start or there are few contractions at the time of hospitalization, 10 oxytocin units will be induced.

Category

Treatment - Drugs

3

Description

Control group: In this group, no action will be taken before hospitalization for delivery, in case of non-onset of labor pains or low contractions of labor delivery, 10 units of oxytocin will be administered.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Valiasr Hospital

Full name of responsible person

Parisa Heydari Babdehooi

Street address

Bafq. valiasr Town

City

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8971717479

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parisa.heydary@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr MohamadAli Sahraiyan

Street address

Tohid Town, Doctor Mirkhani Ave

City

Tehran

Province

Tehran

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1419733171

Phone

+98 21 6105 4000

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parisa.heydari@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Parisa Heydari

Position

Midwife

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No.15, Shahid Tafakori Ave. Shohada Town

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Parisa Heydari
Position
Midwife
Latest degree
Bachelor
Other areas of specialty/work
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Person responsible for updating data

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Bachelor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available