

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effect of oral Evening Primrose Oil on cervical ripening and pregnancy outcomes in nulliparous women

Protocol summary

Summary

Objectives: The aim of this study is to determine the effect of oral Evening Primrose Oil on cervical ripening and pregnancy outcomes on nulliparous women. **Study population:** Healthy women with low-risk pregnancy and gestational age (40 weeks) (40 weeks + 6days) for prenatal care refer to the prenatal clinic in shahid Akbar Abadi Hospital in 1394. **Study groups :** Two groups including drug (oral capsule 1000 mg of Evening Primrose Oil) and placebo(oral capsules 50 mg of gelatin). **Sample size:** 80 persons **Blinding and randomization:** This study will be accomplished randomized Triple-blind clinical trial. **Trial phase:** In this study does not apply **Setting and conduct:** At first for each of women with low risk pregnancy; gestational age 40 weeks to (40 weeks + 6days) based on LMP or ultrasound in first trimester of pregnancy; cervical bishop score less than 4; normal BPP and NST, the demographic questionnaire accompanying with initial examinations, including the mother's vital signs, the fetal heart rate, uterine contractions and cervical Bishop score will be completed. **Exclusion criteria** are mothers who consume them is less than two capsule per day; appears possible side effects of drugs such as headache; nausea; diarrhea and etc. Then each of the participants takes a bottle containing 14 oral capsule 1000 mg of Evening Primrose Oil (2 capsules every 12 hours daily for a weak) or placebo containing 14 oral capsules 50 mg, including gelatin in identical bottles. After the capsules are taken or if because of alarming symptoms like leakage; bleeding; decreased fetal movement; severe abdominal pain the patient goes to hospital, Researcher will go to beside of mothers and record complete information and examination in questionnaire. When mother go to delivery room, vaginal to calculate the Bishop score will record and draw partograph. **Main outcome measures** including Primary : Ripening Of cervix, secondary: during of labor stages; during of active phase; Type of delivery; apgar score in first and fifth minutes of born and

neonatal transport to NICU; Induction and The duration of using oxytocin till the active phase the two groups were compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507022248N17**

Registration date: **2015-08-19, 1394/05/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-08-19, 1394/05/28

Registrant information

Name

Fereshteh Jahdi

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Iran University of Medical Science+Vice Chancellor for research of the international branch of Iran University of Medical Science

Expected recruitment start date

2015-07-27, 1394/05/05

Expected recruitment end date

2015-11-26, 1394/09/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral Evening Primrose Oil on cervical ripening and pregnancy outcomes in nulliparous women

Public title

Effect of Evening Primrose Oil on cervical ripening and pregnancy outcomes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterias: cephalic presentation; alive fetus; with gestational age 40 weeks to (40 weeks + 6 days) based on LMP or ultrasound in first trimester; Normal patterns of fetal heart rate; Without uterine contractions; cervical bishop score less than 4 intact membranous; Maternal height more than 150 cm; non-addicted persons; normal adjusted BPP at the time of inclusion; An ultrasound of the placental grading; weight of fetus between 2500-4000 grams based on physical examination or ultrasonography; Low-risk pregnancy (have no known surgical and internal disease or pregnancy complication such as previa, abruption, preeclampsia , no known fetal problems; Avoiding the enema, Intercourse, laxatives, the use of herbal medicines, chemical or traditional methods for induction of labor; Lack of vaginal examination 24 hours before the beginning till end of the study; Exclusion criterias: appears possible side effects of drugs such as headache, nausea, diarrhea and etc, those who consume them is less than two capsule per day, withdrew from the partnership at any stage of the study.

AgeFrom **18 years** old to **35 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **80****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

People will be allocated randomly in one of two groups primrose capsules and placebo. At first, the names of each of the two groups are written on paper and placed in a separate envelope. The first will be removed one of

the envelopes the next person will be in the other group and again, the third will be removed one of the envelopes the next person will be in the other group. In this way people will be located in one of two groups until the completion of the sample size .

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of the Iran University of Medical Sciences

Street address

Hemmat freeway (beside Milad Tower), Tehran

City

Tehran

Postal code**Approval date**

2015-07-06, 1394/04/15

Ethics committee reference number

IR.IUMS.REC.1394. 26090

Health conditions studied**1****Description of health condition studied**

Ripening of cervix

ICD-10 code

O60-O75

ICD-10 code description

Complications of labour and delivery

Primary outcomes**1****Description**

Ripening Of cervix

Timepoint

During the first week of intervention and labor

Method of measurement

bishop score Table

Secondary outcomes**1****Description**

duration of first, second and third stages of labor

Timepoint

During the first week of intervention and labor

Method of measurement

chronometer/Examination /check list/observation

2

Description

Type of delivery

Timepoint

During the first week of intervention and labor

Method of measurement

End of study/observation

3

Description

infant apgar score

Timepoint

first and fifth minute after delivery

Method of measurement

7 and more, under 7(According to Apgar table)

4

Description

neonatal transport to NICU

Timepoint

During the first 24 hours after childbirth

Method of measurement

check list

5

Description

Induction

Timepoint

During the labor

Method of measurement

check list/observation

6

Description

The duration of using oxytocin in the active phase

Timepoint

During labor

Method of measurement

chronometer/check list/observation

Intervention groups

1

Description

Oral Evening primrose capsules, from (40 weeks) to (40 +6 weeks) , 2 capsules of1000 mg every 12 hours daily for a week (Manufacturing by Traditional Medicine Research Center Shahed University)

Category

Treatment - Drugs

2

Description

Placebo capsule containing gelatin, 50 mg, 2 capsules every 12 hours daily for a week (Manufacturing by Traditional Medicine Research Center Shahed University)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Akbar Abadi Hospital

Full name of responsible person

mahnaz kalati

Street address

Molavi Street, Tehran.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of the international branch of Iran University of Medical science

Full name of responsible person

Dr.mohamad sadegh ghasemi

Street address

Hemmat freeway (beside Milad Tower), Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of the international branch of Iran University of Medical science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

The international branch of Iran University of Medical Sciences and Health

Full name of responsible person

mahnaz kalati

Position

Student of MSc, mail partner of research

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

School of Nursing and Midwifery, Iran University of Medical Sciences

Full name of responsible person

Fereshte Jahdi

Position

master of science in midwifery

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The international branch of Iran University of Medical Sciences and Health

Full name of responsible person

mahnaz kalati

Position

Student of MSc, mail partner of research

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty