# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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
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Iran (Islamic Republic of)
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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 begining 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.
**Age**
From **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 Heath
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Student of MSc, mail partner of research
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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*