Clinical Trial Protocol
Iranian Registry of Clinical Trials
14 Oct 2020

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 + 6 days) 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 week) 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
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Tehran University of Medical Sciences
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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
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 criteria: 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 criteria: 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
O60-075

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 of 1000 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
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Hemmat freeway (beside Milad Tower), Tehran
City
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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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mahnaz kalati
Position
Student of MSc, mail partner of research
Other areas of specialty/work
Person responsible for updating data

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Person responsible for scientific inquiries

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master of science in midwifery
Other areas of specialty/work
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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