Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

the comparison of oral and vaginal evening primrose oil on cervical ripening in late term pregnancy in nulliparous women

Protocol summary

Study aim

The aim of this study is to determine the effect of oral and vaginal Evening Primrose Oil on cervical ripening and pregnancy outcomes on nulliparous women.

Design

90 healthy women with low-risk pregnancy and gestational age (40 weeks to 42 weeks) admitted to pregnancy delivery in Ahvaz Sina Hospital in 1396 will be included in the study. These people randomly blocked are divided into three groups.

Settings and conduct

This study was conducted as a randomized, triangulated clinical trial. when each of participants go to delivery room take two capsules that one of them is vaginal and one of them take oral.if participant will be in placebo group both of capsules is gelatin and if participant in vaginal group take vaginal capsule 1000mg evening primrose oil and one capsule gelatin in oral;if participant in oral group take oral capsule 1000mg evening primrose oil and vaginal gelatin capsule;after this will started induction with oxytocin.after start induction researcher will go to beside of mother and record complete information and examination in questionnaire,vaginal to calculate the Bishop score will record and draw partograph.

Participants/Inclusion and exclusion criteria

Inclusion criteria included cephalic presentation; alive fetus; with gestational age 40 weeks to42 weeks 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; Low-risk pregnancy (have no known surgical and internal disease or pregnancy complication such as previa, abruption, preeclampsia , no known fetal problems. Non-inclusion criteria included consumption of laxatives, the use of herbal medicines, chemical or traditional methods for induction of labor.

Intervention groups

Study groups : Three groups including drug 1 (oral capsule 1000 mg of Evening Primrose Oil and a gelatin capsule orally) drug 2 (vaginal capsule 1000 mg of evening primrose oil and a gelatin capsule orally) and placebo(oral and vaginal capsules 50 mg of gelatin)

Main outcome variables

Cervical preparation, Secondary: Duration of labor stages; Active phase; Type of delivery; Apgar score of the first and fifth minutes; Duration of the use of medication for induction of labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171015036793N2**
Registration date: **2018-02-14, 1396/11/25**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-14, 1396/11/25**
Update count: **0**

Registration date

2018-02-14, 1396/11/25

Registrant information

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Recruitment status

Recruitment complete

Funding source

jondishapur university of medical science

Expected recruitment start date
2017-07-27, 1396/05/05
Expected recruitment end date
2018-02-20, 1396/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
the comparison of oral and vaginal evening primrose oil on cervical ripening in late term pregnancy in nulliparous women

Public title
effect of oral and vaginal evening primrose oil on cervical ripening and pregnancy outcomes and compare together
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
cephalic presentation alive fetus with gestational age 40 weeks to42 weeks 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 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 Avoiding the Intercourse
Exclusion criteria:
consumption of laxatives, the use of herbal medicines, chemical or traditional methods for induction of labor
Age
From **15 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
The sampling will be done in a sequential non-probabilistic manner, which will be selected as a sample from the start of the study for all pregnant women who have the criteria for entering the study and will continue to reach the final sample size. The assignment of participants to each of the study groups will be done randomly by block method using 6 blocks. In this study, 15 blocks of 6 were designed, in each block, the ratio of the presence of 3 groups in these blocks was 2- 2-2 and is equal.
Blinding (investigator's opinion)
Single blinded
Blinding description
In order to blind people in the oral intervention group, the placebo will be used vaginally, and in the vaginal intervention group, the placebo will be used orally. In order to ensure the reduction of the occurrence of information malpractice and the hypnotic effect of drugs, this double-blind, double-blind trial designed to keep both patients and the treatment staff of the type of treatment intended to be kept unaware.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of Ahvaz Jundishapour University of Medical Sciences
Street address
Ahvaz Jundishapour University of Medical Sciences, Golestan street; Ahvaz
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Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2017-05-22, 1396/03/01
Ethics committee reference number
IR.AJUMS.REC.1396.166

Health conditions studied

1

Description of health condition studied
complications of labor and delivery
ICD-10 code
O61.0
ICD-10 code description
Failed medical induction of labour

Primary outcomes

1

Description
ripening of cervix
Timepoint
during the labor
Method of measurement
bishop score table

Secondary outcomes

1

Description
duration of first, second and third stage of labor
Timepoint
during the labor
Method of measurement
chronometer/examination/check list/observation

2

Description
type of delivery
Timepoint
during the labor
Method of measurement
Separation into cesarean section and normal according to how the embryos leave

3

Description
infant APGAR score
Timepoint
first and fifth minute after delivery
Method of measurement
apgar table

Intervention groups

1

Description
Intervention group: drug group 1, Oral capsule of 1000 mg of primrose oil and one vaginal gelatin capsule beginning admit participant in delivery room(manufacturing by Barrij essence company)
Category
Treatment - Drugs

2

Description
Intervention group: Drug group 2 (vaginal capsule 1000 mg of evening primrose oil and a gelatin capsule orally)
Category
Treatment - Drugs

3

Description
Control group: Placebo (oral capsule 50 mg gelatin)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina Hospital
Full name of responsible person
Sara Dehghan
Street address
Kute abdollah, Ahvaz,
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
vice chancellor for research of the Ahvaz Jundishapour University of Medical Sciences
Full name of responsible person
Dr. Behzad Sharifmakhmalzadeh
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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 Ahvaz Jundishapour 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
Ahvaz Jundishapour University of Medical Sciences

Full name of responsible person
Fatemeh Khatami

Position
MSc student of Midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

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School of Nursing and Midwifery, Ahvaz Jundishapour University of Medical Sciences

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Position
Doctor of Reproductive Health and Midwifery

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Not applicable

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