Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Study of the effect of vaginal Evening Primrose Oil capsule versus placebo on cervical ripening and delivery outcomes in nulliparous women: a double-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of vaginal Evening Primrose Oil capsule versus placebo on cervical ripening and delivery outcomes in nulliparous women

Design
This is a double-blind randomized clinical trial, phase II, in which 50 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible nulliparous women who will refer to Fatemieh Hospital during the study period will be enrolled in the trial

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 18 to 45 years; Nulliparous; Cephalic presentation of embryo and alive with normal patterns of embryonic heart rate; Embryonic weight of 2500 to 3500 g; Gestational age of 38 to 39 weeks; Bishop score of 4 or lower Exclusion criteria: Sensitivity of herbal medications; Amniotic fluid disorder; Preeclampsia; Diabetes; Placenta aberration; Placenta Previa; Indication of cesarean

Intervention groups
Intervention group: Vaginal Evening Primrose Oil capsule 500 mg twice with 2 hours interval during delivery
Control group: Vaginal placebo capsule twice with 2 hours interval during delivery

Main outcome variables
Primary outcome: Cervical ripening Neonate Apgar score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N231**
Registration date: **2018-08-24, 1397/06/02**
Registration timing: **prospective**
Last update: **2018-08-24, 1397/06/02**
Update count: **0**

Registration date
2018-08-24, 1397/06/02

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-09-23, 1397/07/01

Expected recruitment end date
2019-09-23, 1398/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study of the effect of vaginal Evening Primrose Oil capsule versus placebo on cervical ripening and delivery outcomes in nulliparous women: a double-blind randomized clinical trial

Public title

The effect of vaginal Evening Primrose Oil capsule versus placebo on cervical ripening and delivery outcomes in nulliparous women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 45 years; Nulliparous; Cephalic presentation of embryo and alive with normal patterns of embryonic heart rate; Embryonic weight of 2500 to 3500 g; Gestational age of 38 to 39 weeks; Bishop score of 4 or lower

Exclusion criteria:

Sensitivity of herbal medications; Amniotic fluid disorder; Preeclampsia; Diabetes; Placenta aberration; Placenta Previa; Indication of cesarean

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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Province

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6517838695

Approval date

2018-07-21, 1397/04/30

Ethics committee reference number

IR.UMSHA.REC.1397.323

Health conditions studied

1

Description of health condition studied

Delivery outcomes

ICD-10 code

Z34.83

ICD-10 code description

Encounter for supervision of other normal pregnancy, third trimester

Primary outcomes

1

Description

Cervical ripening

Timepoint

During delivery

Method of measurement

With physical examination

2

Description

Neonate Apgar score

Timepoint

In the first and fifth minutes after delivery

Method of measurement

With physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Vaginal Evening Primrose Oil capsule 500 mg twice with 2 hours interval during delivery

Category

Treatment - Drugs

2

Description
Control group: Vaginal placebo capsule twice with 2 hours interval during delivery
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemieh Hospital
Full name of responsible person
Dr Farideh Kazemi
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School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Hamedan 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
Hamedan University of Medical Sciences
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PhD in Midwifery
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Person responsible for updating data

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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