

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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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

City

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Province

Hamadan

Postal code

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

Hamedan University of Medical Sciences

Full name of responsible person

Dr Saeid Bashirian

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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

Full name of responsible person

Dr Farideh Kazemi

Position

PhD in Midwifery

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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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