Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Evening Primrose Oil on Postpartum Blue in Primiparus Women

Protocol summary

Summary

This double-blind clinical trial study was conducted in 2012-2013 in Ahvaz health centers to determine the effects of Evening primrose oil on prevention, intensity and length of postpartum blues among 132 nulipara pregnant women (66 intervention and 66 control) aged between 18-35. Inclusion criteria involved mothers in their 36th week of gestational age and older while the exclusion criteria included mothers who had a history of systemic diseases, infertility, mental disorders, unwanted pregnancy or using similar supplements in the third trimester. Also, excluded from the study were those having abnormal pregnancy/birth or newborns with Apgar score less than 0.7, and those requiring hospitalization during the study. Subjects in the intervention group and the control group received Evening primrose oil and placebo respectively at the outset of the 37th week of pregnancy until two weeks after delivery. The samples were then evaluated on days 4, 10 and 14 postpartum and the data was analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013052513452N1**
Registration date: **2015-10-02, 1394/07/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-10-02, 1394/07/10

Registrant information

Name

Soghra Nikoomazhab

Name of organization / entity

Ahvaz Jundishapour University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3552 3181

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jondishapour University of Medical Sciences

Expected recruitment start date

2012-06-09, 1391/03/20

Expected recruitment end date

2013-07-11, 1392/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Evening Primrose Oil on Postpartum Blue in Primiparus Women

Public title

The effect of Evening Primrose Oil on Postpartum Blue

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Gestational age 36 weeks or older; Being the first and the only partner; Exclusion criteria: Requiring intervention to terminate pregnancy; Giving birth to babies with Apgar score less than 0.7; Requiring hospitalization of the newborn; Having domestic problems; Having history of infertility and/or systemic diseases; Using similar supplements in the 3rd trimester; Having unwanted pregnancy; Getting a score above 23 in general health questionnaire;

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: **132**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ahvaz Jondishapour University of Medical Sciences
Street address
Golestan Bulevard
City
Ahvaz
Postal code
Approval date
2010-09-23, 1389/07/01
Ethics committee reference number
ETH505

Health conditions studied

1

Description of health condition studied
Postpartum Blue
ICD-10 code
0260.9
ICD-10 code description
Pregnancy-related condition, unspecified

Primary outcomes

1

Description
maternal blue
Timepoint
on days 4th, 10th and 14th postpartum
Method of measurement
edinburg scale

Secondary outcomes

1

Description
some sideffects like diarea or bloating
Timepoint
daily
Method of measurement
daily conection for taking history and clinical and physical examinatiom

Intervention groups

1

Description
Using 1 placebo softgel daily in control group
Category
Prevention

2

Description
using 1 gr evening primrose oil daily in intervention group
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz East Health center
Full name of responsible person
Soghra Nikoomazhab
Street address
Behbehani bulvar
City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jondishapour University of Medical Sciences
Full name of responsible person
Nader Saki
Street address
Vice Chancellor for Research and Technology
City
Ahvaz
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz Jondishapour University of Medical Sciences
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
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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