Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of evening primrose oil capsules on postpartum pain in multiparous women

Protocol summary

Study aim
Determining the effect of evening primrose oil capsule on postpartum pain in multiparous women

Design
The clinical trial will be a parallel (placebo and control groups), triple-blind, randomized, phase 3 study on 90 pregnant women. Random number table will be used for randomization.

Settings and conduct
This study will be performed in Amolbinin Hospital in Mashhad. In both intervention and placebo groups, post delivery pain will be measured. The first dose of the drug will be given at least two hours after delivery. The pain will be measured one hour after the intervention. The two groups will receive the capsules 4 times every 8 hours. At each intervention, the pain will be measured and recorded one hour before and one hour after. The control group will receive routine painkillers if pain is expressed.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 18-35 years old, single pregnancy; gestational age 37-42 weeks, infant weight 4000-2500 grams, normal delivery; gravid 2-5, no anesthesia, no previous uterine surgery, second and third stage of normal delivery, no grade 3 and 4 rupture , Pain intensity 4 and more Exclusion criteria: Pain relief, allergy to evening primrose, serious side effects

Intervention groups
Intervention group: evening primrose oil capsules. Control group: routine care and 500 mg acetaminophen for pain if requested

Main outcome variables
postpartum pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210217050394N1**
Registration date: **2021-03-08, 1399/12/18**
Registration timing: **prospective**

Last update: **2021-03-08, 1399/12/18**
Update count: **0**

Registration date
2021-03-08, 1399/12/18

Registrant information

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Maryam Amin

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-03-10, 1399/12/20

Expected recruitment end date
2021-07-16, 1400/04/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of evening primrose oil capsules on postpartum pain in multiparous women

Public title
Evaluation of the effect of evening primrose oil capsules

on postpartum pain in multiparous women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Being Iranian mother age between 18-35 years singleton pregnancy with gestational age 37-42 weeks normal delivery live and seemingly healthy baby baby weight between 4000-2500 grams Normal delivery gravid 3-5 No use of narcotics and spinal and epidural anesthesia during labor No cesarean section or previous uterine surgery The second and third stages of normal delivery Absence of medical disease and no grade 3 and 4 perineal and vaginal tears Lack of sensitivity to medicinal plants and acetaminophen Start breastfeeding until the first two hours after delivery and continue breastfeeding Pain intensity (based on visual scale) 4 and more within 2 hours after delivery

Exclusion criteria:

The mother's unwillingness to participation Allergy to medicinal plants Medical and midwifery problems First pregnancy Multiplication Mother age should not be between 18-35

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling in the midwifery clinic of Umm Al-Banin hospital will be done in an easy method, based on the inclusion and exclusion criteria, and using a simple randomization method, random allocation of samples will be done in different groups. Randomization method will be as follow: It is performed that the assignment sequence will be written before the beginning of the research. Given that 3 groups will be studied and each letter will be assigned to a group (A evening primrose capsule, B placebo and C control group with routine care). Randomization will be performed using Research Randomizer software, then inside the sealed and opaque packages, the type of intervention will be written based on the allocation sequence and packages will be numbered.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Capsules will be encoded by the pharmacist. The capsules will be divided and numbered in opaque and sealed envelopes. Researchers and mothers will be unaware of group codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Khorasan Razavi, Mashhad, Daneshgah St., Ph.D. Intersection, Ibn Sina St., School of Nursing and Midwifery

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2021-01-26, 1399/11/07

Ethics committee reference number

IR.MUMS.NURSE.REC.1399.083

Health conditions studied

1

Description of health condition studied

Postpartum pain

ICD-10 code

Z39

ICD-10 code description

Encounter for maternal postpartum care and examination

Primary outcomes

1

Description

Postpartum pain in multiparous women

Timepoint

Beginning and end of the study and during the first 24 hours of labor - every 8 hours - one hour before and one hour after the intervention.

Method of measurement

McGill Pain Questionnaire and Visual Pain Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 1000 mg evening primrose oil capsule and made by Barij Essential Oil Company, available in the market, based on previous studies in the field of gynecology and obstetrics and with the advice of a pharmacist, its number and amount of use will be determined and considered for intervention at least 2 hours after delivery. The first dose will be given and the pain will be measured and recorded again one hour after taking the medicine. The intervention group will receive the capsule 4 times every 8 hours. At each intervention, pain intensity will be measured and recorded one hour before and one hour after. One hour after each intervention, if the pain will persist and the mothers request painkillers, a 500 mg acetaminophen tablet is given and recorded.
Category
Treatment - Drugs

2

Description
Placebo group: 1000 mg capsule containing paraffin, very similar to evening primrose capsule, at least 2 hours after delivery, the first dose will be given and one hour after taking the drug, the pain will be measured and recorded again. The group will receive the capsule 4 times every 8 hours. At each intervention, pain intensity will be measured and recorded one hour before and one hour after. One hour after each intervention, if the pain will persist and the mother requests painkillers, an acetaminophen 500 mg tablet is given and recorded.
Category
Treatment - Drugs

3

Description
Control group: In the control group, no intervention will be performed and if pain is expressed, they will receive routine analgesia (acetaminophen 500 mg).
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Umm Al-Banin Hospital
Full name of responsible person
Dr. Masoumeh Mirtimouri
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Mashhad, Zarrineh Crossroads, Ayatollah Behjat Street, corner of Ayatollah Behjat 16
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Maryam Amin
Position
Student
Latest degree
Bachelor

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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