

# 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

###### Name

Maryam Amin

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3761 7082

###### Email address

aminm982@mums.ac.ir

##### 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

##### Street address

Mashhad, Zarrineh Crossroads, Ayatollah Behjat Street, corner of Ayatollah Behjat 16

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

919686447

##### Phone

+98 51 3223 1061

##### Fax

+98 51 3223 1444

##### Email

oah.it@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohsen Tafaghodi

##### Street address

School of Nursing and Midwifery.Ibn Sina St

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913199

##### Phone

+98 51 3859 1513

##### Email

TafaghodiM@mums.ac.ir

##### 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

**Other areas of specialty/work**

Midwifery

**Street address**

School of Nursing and Midwifery Mashhad Ibn Sina St.

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

+98 51 3859 1511

**Email**

AminM982@mums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Samira Ebrahimzadeh Zagmi

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Midwifery

**Street address**

Mashhad, Ibn Sina St., School of Nursing and Midwifery

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

+98 51 3859 1511

**Email**

EbrahimzadehZS@mums.ac.ir

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

Mashhad University of Medical Sciences

**Full name of responsible person**

Maryam Amin

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Midwifery

**Street address**

Ibn Sina St., School of Nursing and Midwifery

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913199

**Phone**

+98 51 3859 1511

**Email**

AminM982@mums.ac.ir

**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