

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Studying the effects of Celecoxib as monotherapy in the treatment of postpartum depression with mild intensity to the average: response to treatment of Celecoxib by area Brain-Derived Neurotrophic Factor (BDNF) and inflammatory cytokines (TNF α , IFN γ , IL-1A, IL-1B IL-6, IL-8)

Protocol summary

Study aim

Studying the effects of Celecoxib as monotherapy in the treatment of postpartum depression with mild intensity to the average

Design

Randomized double blind and placebo-controlled clinical trial

Settings and conduct

The study will be performed on women with mild to moderate postpartum depression Attending Roozbeh Hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages of 18 to 45 years - Having mild to moderate depression according to Hamilton Depression Rating Scale (HAM-D or HDRS). Exclusion criteria: Having severe depression according to Hamilton Depression Rating Scale (HAM-D or HDRS) - Addiction to drugs - Addiction to alcohol - Presence of Thyroid disease - Receiving any antidepressant medications during past one month prior to the trial - Receiving Electroconvulsive therapy during past two months prior to the trial - Any other diagnosis according to axis-1, DSM-5 - Having a risk of suicide based on doctor's clinical judgement or having a score of >2 in suicide item of Hamilton Depression Rating Scale (HAM-D or HDRS) - Concomitant use of medications that increase the risk of gastrointestinal bleeding - Presence of cardiovascular disease - Pregnant and lactating women - Risk of child murder

Intervention groups

Women who score below 18 based on Hamilton Depression Rating Scale (HAM-D or HDRS) will be considered as mild to moderate depressed patients and randomly divided into two groups. The intervention group (25 patients) will receive Celecoxib (200 mg BID) for 8 weeks. The control group (25 patients) will receive

placebo for 8 weeks (BID).

Main outcome variables

Severity of depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090117001556N125**

Registration date: **2020-05-17, 1399/02/28**

Registration timing: **prospective**

Last update: **2020-05-17, 1399/02/28**

Update count: **0**

Registration date

2020-05-17, 1399/02/28

Registrant information

Name

Shahin Akhondzadeh

Name of organization / entity

Roozbeh Psychiatric Hospital, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 2222

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effects of Celecoxib as monotherapy in the treatment of postpartum depression with mild intensity to the average: response to treatment of Celecoxib by area Brain-Derived Neurotrophic Factor (BDNF) and inflammatory cytokines (TNF α , IFN γ , IL-1A, IL-1B IL-6, IL-8)

Public title

The effects of Celecoxib in the treatment of postpartum depression with mild intensity to the average

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 to 45 Having mild to moderate depression according to Hamilton Depression Rating Scale (HAM-D)

Exclusion criteria:

Having severe depression according to Hamilton Depression Rating Scale (HAM-D or HDRS) Addiction to drugs Addiction to alcohol Presence of Thyroid disease Receiving any antidepressant medications during past one month prior to the trial Receiving Electroconvulsive therapy during past two months prior to the trial Any other diagnosis according to axis-1, DSM-5 Having a risk of suicide based on doctor's clinical judgement or having a score of >2 in suicide item of Hamilton Depression Rating Scale (HAM-D or HDRS) Concomitant use of medications that increase the risk of gastrointestinal bleeding Presence of cardiovascular disease Pregnant and lactating women Risk of child murder

Age

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

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted block randomization: using A and B blocks with n=4; AABB, ABAB, ABBA, BABA, BAAB, BBAA. We randomly use the blocks to achieve total sample size. ("A" and "B" are the study groups)

Blinding (investigator's opinion)

Double blinded

Blinding description

The participants, care providers and outcome assessors will be blind regarding grouping. All the participants believe that they are taking the main medication (the participants who are taking placebo are not aware of it). Care providers and outcome assessors do not know which participants have received the main medication and which participants have received placebo. Thus, there is no orientation in their work process.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Qhods St., Keshavarz Blvd.

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Tehran

Postal code

1417653761

Approval date

2020-03-17, 1398/12/27

Ethics committee reference number

IR.TUMS.VCR.REC.1398.1060

Health conditions studied**1****Description of health condition studied**

Postpartum depression

ICD-10 code

O90.6

ICD-10 code description

Postpartum mood disturbance

Primary outcomes**1****Description**

Severity of depression

Timepoint

Baseline and weeks 2, 4, 6, and 8

Method of measurement

By Hamilton Depression Rating Scale (HAM-D or HDRS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Celecoxib capsule (Daroopakshh, Tehran), 200 mg BID, oral (p.o.), for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: Placebo (BID), oral (p.o.), for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Roozbeh hospital

Full name of responsible person

Prof. Mohammad Reza Mohammadi

Street address

Roozbeh Hospital, South Kargar Street

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mohammadimr@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhondzadeh

Position

Professor of clinical psychopharmacology

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The data will be distributed through final report

When the data will become available and for how long

5 years from 2021 to 2026

To whom data/document is available

academic researchers

Under which criteria data/document could be used

users should cite the resource of data

From where data/document is obtainable

Prof Shahin Akhondzadeh

What processes are involved for a request to access data/document

by E mail

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

Tehran University of Medical Sciences

Full name of responsible person

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