

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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 $\alpha$ , IFN $\gamma$ , 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

s.akhond@sina.tums.ac.ir

#### 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 $\alpha$ , IFN $\gamma$ , 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; AAB, 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.

**City**

Tehran

**Province**

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**

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Celecoxib capsule (Daroopaksh, 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1333715914

##### Phone

+98 21 5541 2222

##### Email

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

##### Street address

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1417653761

##### Phone

+98 21 8898 7381

##### Email

msahrai@tums.ac.ir

##### 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

##### Street address

Roozbeh Hospital, South Kargar Street, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1333715914

##### Phone

+98 21 5541 2222

##### Email

s.akhond@sina.tums.ac.ir

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Prof. Shahin Akhondzadeh

##### Position

Professor of clinical psychopharmacology

##### Latest degree

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Roozbeh Hospital, South Kargar Street, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1333715914

**Phone**

+98 21 5541 2222

**Email**

s.akhond@sina.tums.ac.ir

+98 21 5541 2222

**Fax**

+98 21 5541 9113

**Email**

s.akhond@sina.tums.ac.ir

**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**

Shahin Akhondzadeh

**Position**

Professor of clinical psychopharmacology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Roozbeh Hospital, South Kargar Street

**City**

Tehran

**Province**

Tehran

**Postal code**

1333715914

**Phone**