Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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 (TNFα, IFNγ , 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)

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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 (TNFα, IFNγ , 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.
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

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

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Celecoxib capsule (Daroopakhsh, 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
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?
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
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Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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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