Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of Celecoxib on depression induced by COVID-19: A randomized double blind and placebo controlled clinical trial

Protocol summary

Study aim
The effect of Celecoxib on depression in patients with COVID-19

Design
Randomized double blind and placebo-controlled clinical trial

Settings and conduct
The study will be performed on patients with depression induced by COVID-19 attending Imam Khomeini Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18 to 60 years - At least 20 days after the onset of symptoms and 7 days after the last day the patient was symptomatic, the patient should show a score of 14-17 on HDRS (moderate depression). Exclusion criteria: History of depression before infected with COVID-19 - Psychosis - Any other mental disorder in another axis - Taking other psychiatric drugs which can alter cognitive functions - History of ECT in recent two months - Thyroid dysfunctions - Kidney disease - Liver disease - History of cognitive dysfunction or dementia - Pregnant or lactating women - Serious suicidal thoughts (<2 in suicidal HDRS section).

Intervention groups
Intervention group: Patients treated with Celecoxib 100 mg BID for 6 weeks. Control group: Patients treated with placebo BID for 6 weeks. Patients will be evaluated at weeks 0, 3 and 6 by the HDRS.

Main outcome variables
Severity of depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090117001556N142**
Registration date: **2022-03-01, 1400/12/10**
Registration timing: **prospective**
Last update: **2022-03-01, 1400/12/10**
Update count: **0**

Registration date
2022-03-01, 1400/12/10

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
2022-05-22, 1401/03/01

Expected recruitment end date
2024-05-21, 1403/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of Celecoxib on depression induced by COVID-19: A randomized double blind and placebo controlled clinical trial

Public title
The effect of Celecoxib on depression in patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 to 60 years At least 20 days after the onset of symptoms and 7 days after the last day the patient was symptomatic, the patient should show a score of 14-17 on HDRS (moderate depression)

Exclusion criteria:

History of depression before infected with COVID-19 Psychosis Any other mental disorder in another axis Taking other psychiatric drugs which can alter cognitive functions History of ECT in recent two months Thyroid dysfunctions Kidney disease Liver disease History of cognitive dysfunction or dementia Pregnant or lactating women Serious suicidal thoughts (<2 in suicidal HDRS section)

Age

From **18 years** old to **60 years** old

Gender

Both

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

2021-11-28, 1400/09/07

Ethics committee reference number

IR.TUMS.DDRI.REC.1400.055

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Severity of Depression

Timepoint

by Hamilton Depression Rating Scale (HDRS)

Method of measurement

Baseline and weeks 3 and 6

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients treated with Celecoxib 100 mg BID for 6 weeks.

Category

Treatment - Drugs

2

Description

Control group: Patients treated with placebo BID for 6 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Roozbeh hospital

Full name of responsible person
Dr. Mohammad Reza Mohammadi

Street address
Roozbeh Hospital, South Kargar Street, Tehran

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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. Akbar Fotouhi

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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
Dr. Shahin Akhondzadeh

Position
Professor of clinical psychopharmacology

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Roozbeh Hospital, South Kargar Street, Tehran

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Person responsible for updating data

Contact

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Tehran University of Medical Sciences

Full name of responsible person

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Position
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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 2022 to 2027
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