

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jul 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; 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

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

Type of organization providing the funding  
Academic

## 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

**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. Akbar Fotouhi

**Street address**

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

**City**

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**Province**

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**Postal code**

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**Phone**

+98 21 8898 7381

**Email**

afotouhi@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**

## 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

**Street address**

Roozbeh Hospital, South Kargar Street, Tehran

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## Person responsible for scientific inquiries

### Contact

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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**