

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effect of fluvoxamine in preventing neuropsychiatric symptoms of Long COVID syndrome

Protocol summary

Study aim

Determining the effect of fluvoxamine on preventing neuropsychological symptoms of prolonged Covid syndrome

Design

In COVID Clinic, Two groups of COVID patients are matched in terms of age, sex, underlying disease, and disease severity. After randomization, one group receive fluvoxamine, 50 mg tablets twice daily for 10 days along with the main therapy, and the control group receives a placebo. These patients are selected under the direct supervision of a neurologist for appropriate conditions and the absence of contraindications. After 4 weeks from the onset of symptoms, any of the patients who are still in the study will be contacted by phone and will be evaluated for neuropsychological symptoms common in long COVID syndrome including dizziness, fatigue, headache, impaired consciousness, ataxia, seizures Taste, olfactory dysfunction, visual disturbance, myalgia, depression, memory impairment, sleep disturbance, anxiety, autonomic dysfunction and difficulty concentrating. Then the effect of receiving fluvoxamine in the group receiving this drug on the prevention of long-term COVID symptoms is evaluated.

Settings and conduct

The target population of this study is all patients who are referred to the hospitals of the AJA University of Medical Sciences in 2022 due to Covid-19. The main referral environment is COVID clinics.

Participants/Inclusion and exclusion criteria

The target population of this study is all patients who are referred to the hospitals of the AJA University of Medical Sciences in 2022 due to Covid-19. The main referral environment is COVID clinics. Inclusion criteria, Confirmed COVID infection Exclusion criteria, History of psychological disorders or receiving psychological drugs

Intervention groups

Prescription of fluvoxamine for the intervention group and placebo for the control group

Main outcome variables

Frequency of neuropsychological symptoms of Long COVID syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220526054990N1**

Registration date: **2022-06-01, 1401/03/11**

Registration timing: **registered_while_recruiting**

Last update: **2022-06-01, 1401/03/11**

Update count: **0**

Registration date

2022-06-01, 1401/03/11

Registrant information

Name

Ali Ajam

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8835 6498

Email address

a-ajam@alumnus.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-01, 1400/12/10

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of fluvoxamine in preventing neuropsychiatric symptoms of Long COVID syndrome

Public title
Fluvoxamine in Long COVID

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed COVID infection by infectious disease specialist
Age over 15 years
Exclusion criteria:
History of epilepsy
History of mania
History of depression
Use of other antidepressants
Pregnancy and lactation
Kidney dysfunction
Liver dysfunction
History of cardiac arrhythmia
Any drug allergy to fluvoxamine, including skin allergies
Severe side effects of fluvoxamine, including malignant neuroleptic syndrome
Drug interactions with other drugs consumed by the patient

Age
From **15 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **96**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is done by the simple randomization method. In Excel software, a randomization table is created according to the sample size, and the letter A or B is assigned to each number from 1 to the sample size. Each letter indicates a treatment, fluvoxamine or placebo, of which the study designer and the doctor who prescribes the treatment are unaware. The drugs are placed in opaque envelopes by another person who has no other role in the analysis of the study. Patients receive one of the two diets based on the enrollment number.

Blinding (investigator's opinion)
Double blinded

Blinding description
The principal investigator, analyzer, and patients are unaware of the drug given or taken. A third-person unaware of the analysis and the results prepares the placebo and the drug into identical packages.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

AJA University of Medical Sciences

Street address

13th Floor, Block A, Farahzadi Blvd, Headquarters of the Ministry of Health and Medical Education, Simaye Azadi Str., Shahrak-e Gharb

City

Tehran

Province

Tehran

Postal code

1419943471

Approval date

2022-02-21, 1400/12/02

Ethics committee reference number

IR.AJAUMS.REC.1400.302

Health conditions studied

1

Description of health condition studied

Long or Post COVID syndrome

ICD-10 code

U09.9

ICD-10 code description

Post COVID-19 condition occurs in individuals with a history of probable or confirmed SARS CoV-2 infection, usually 3 months from the onset of COVID-19 with symptoms and that last for at least 2 months and cannot be explained by an alternative diagnosis.

Primary outcomes

1

Description

Frequency of any of the neuropsychological symptoms of Long COVID in patients

Timepoint

4 weeks after COVID symptoms onset

Method of measurement

history taking based on a questionnaire prepared by the researcher

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The drug fluvoxamine maleate 50 mg fc tablet made by Jalinous Pharmaceutical Company, every 12 hours for 10 days, after 4 weeks, patients are contacted and asked about the symptoms of Long COVID based on the questionnaire.

Category

Treatment - Drugs

2

Description

Control group: placebo 1 tablet for every 12 hours for 10 days, after 4 weeks, patients are contacted and asked about the symptoms of long quiescence based on a questionnaire.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Ali Ajam

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1781997511

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

-

Street address

Etemad zadeh street, Fatemi-Gharbi Street

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1411718541

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Artesh 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

Ali Ajam

Position

Alumnus

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Full name of responsible person

Ali Ajam

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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

No - There is not 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

Part of the information about the final outcome after being unidentifiable can be shared

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Accessible to all academic and scientific researchers

Under which criteria data/document could be used

The analysis is allowed on the delivered data

From where data/document is obtainable

Ali Ajam, ali.ajam1374@gmail.com

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

The request will be answered within one week after the request

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

Tehran University of Medical Sciences

Full name of responsible person

Ali Ajam

Position

Alumnus

Latest degree

Medical doctor

Other areas of specialty/work

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