Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 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)

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+98 21 8835 6498

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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 lactationK 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 neuropsycological 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
Street address
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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
City
Tehran
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Tehran
Postal code
1411718541
Phone
+98 21 8609 6350
Email
behsan@ajaums.ac.ir
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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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
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