

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Effect of fluvoxamine medicine on cytokine level of COVID-19 patients, hospitalized in ICU ward

Protocol summary

Study aim

Evaluating the IL-6 level in COVID-19 patients hospitalized in Intensive Care Unit (ICU), after consuming Fluvoxamine. Comparing the IL-6 level in two groups of COVID-19 patients, hospitalized in ICU, with the history of consuming Fluvoxamine and without it.

Design

Clinical trial with two control and intervention groups, which are dedicated randomly. 20 patients participate in each group and the intervention group is being treated by Fluvoxamine.

Settings and conduct

The place of work is Massih Daneshvari Hospital, which 40 hospitalized patients in ICU ward due to COVID-19 are selected by accessible method of sampling. The demographic researcher made questionnaire is completed by all of the sample group at first. Then the level of Erythrocyte Sedimentation Rate (ESR), Interlukin-6 (IL-6) and C-Reactive Protein (CRP) are measured in them. Then they are dedicated to experimental and control groups. The experimental group receives fluvoxamine drug, but the control group does not. The level of ESR, IL-6 and CRP are measured again in all 40 patients when discharging from the ICU.

Participants/Inclusion and exclusion criteria

Patients who had been hospitalized in ICU due to COVID-19 participate in the study. Patients who have been hospitalized in any hospital wards due to any diseases, except COVID-19, would not enter to the research project.

Intervention groups

The intervention group receive fluvoxamine and the control group does not receive it. The fluvoxamine dosage starts from 50 mg daily. It raises up to 300 mg per week, depending on the patient tolerance to drug. All of the patients are daily visited by the psychiatrist for psychological symptoms and also possible fluvoxamine side effects. They also visit by psychiatrist, for tapering or stopping the fluvoxamine consumption, after

discharging from ICU.

Main outcome variables

Measuring the level of CRP, IL-6 and ESR by blood pressure.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20131115015405N4**

Registration date: **2020-10-03, 1399/07/12**

Registration timing: **retrospective**

Last update: **2020-10-03, 1399/07/12**

Update count: **0**

Registration date

2020-10-03, 1399/07/12

Registrant information

Name

Mitra Safa

Name of organization / entity

Massih Daneshvari Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 2712 2607

Email address

m.safa@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-09-05, 1399/06/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of fluvoxamine medicine on cytokine level of COVID-19 patients, hospitalized in ICU ward

Public title
Effect of fluvoxamine on cytokine in COVID-19 patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent Being conscious Definite diagnosis of COVID-19 in medical records of the patient Age over 18 years old Normal serum level of Creatinine, Blood Urea Nitrogen, White Blood Cell, Potassium, Sodium and Fasting Blood Sugar
Exclusion criteria:
Being pregnant. Existence of ASA, Warfarin, MAOI, Lithium, Clomipramine, NSAIDs, Methadone, Capropril, Diltiazem and Zolpidem drugs in medical files of the patient. Simultaneous consumption of any kind of alcohol or substance.

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
simple randomization method is applied, which the written names of the participants are placed in a container, separately. Then one of the members of research team choose 20 of them randomly, as the intervention group, without the possibility of seeing the names. The rest of 20 names are allocated to control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Research Institute of Tuberculosis and Lung Diseases

Street address

Massih Daneshvari Hospital, Daar-Abad, Niavaran, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1956944413

Approval date

2020-09-16, 1399/06/26

Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.177

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

Interlukine - 6 (IL-6) level will be measured in COVID-19 patients.

Timepoint

The Interlukine - 6 level will be measured both before the consumption of Fluvoxamine drug and when discharging from the ICU ward.

Method of measurement

Measuring kit of Interlukine - 6 by blood test.

2

Description

Erythrocyte Sedimentation Rate (ESR) level will be measured in COVID-19 patients.

Timepoint

The Erythrocyte Sedimentation Rate (ESR) level will be measured both before the consumption of Fluvoxamine drug and when discharging from the ICU ward.

Method of measurement

Measuring kit of Erythrocyte Sedimentation Rate (ESR) by blood test.

3

Description

C-Reactive Protein (CRP) level will be measured in COVID-19 patients.

Timepoint

The C-Reactive Protein (CRP) level will be measured both before the consumption of Fluvoxamine drug and when discharging from the ICU ward.

Method of measurement

Measuring kit of C-Reactive Protein (CRP) by blood test.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group will be treated by Fluvoxamine drug. The drug dosage will be increased up to 300 mg daily depending on the patients tolerance to the drug. At first, 50 mg will be prescribed per night. after 2 days, 100 mg will be prescribed per night. After 4 days, 100 mg will be prescribed per afternoon and 100 mg will be prescribed per night. After 4 days, 100 mg will be prescribed per morning, 100 mg will be prescribed per afternoon and 100 mg will be prescribed per night. Pharmaceutical companies including Abidi and Sobhan produce Fluvoxamine drug in Iran. Thus, the Fluvoxamine produced by each of the mentioned pharmaceutical companies will be used in the current project.

Category

Treatment - Drugs

2

Description

Control group: This group will not receive Fluvoxamine drug. But all of the members undergo COVID-19 treatment in Intensive Care Unit under the supervision of the specialist physician, like the intervention group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Massih Daneshvari Hospital

Full name of responsible person

Mitra Safa

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Massih Daneshvari Hospital, Daar-Abad, Niavaran, Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mitra Safa

Street address

Massih Daneshvari Hospital, Daar-Abad, Niavaran, Tehran, Iran

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mitra Safa

Position

Professor, head of psychiatry department in Massih Daneshvari hospital

Latest degree

Specialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mitra Safa

Position

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mitra Safa

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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All participants data will be presented as article, when
finalizing the work, because their data does not contain
identification information.

When the data will become available and for how long

Accessing to data would be possible after publication of
the article.

To whom data/document is available

All academic researchers can access to data.

Under which criteria data/document could be used

When the article is published, all academic researchers
can send a request for accessing the data, then the
results will be announced after some considerations.

From where data/document is obtainable

The corresponding author and his/her email address will
be determined in published article, which every one who
needs the data can use it.

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

When the applicant send a request through email
address, the results will be announced in a week.

Comments