Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Aug 2022

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 Ureh 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
Street address
Massih Daneshvari Hospital, Daar-Abad, Niavaran, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2712 3000
Email
pr.nritld@sbmu.ac.ir

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
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2712 2607
Email
mitra.safa@yahoo.com
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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Massih Daneshvari Hospital, Daar-Abad, Niavaran, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2712 2607
Email
mitra.safa@yahoo.com

Person responsible for scientific 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
Street address
Massih Daneshvari hospital, Daar-Abad, Niavaran, Tehran, Iran.
City
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Province
Tehran
Postal code
1956944413
Phone
+98 21 2712 2607
Email
mitra.safa@yahoo.com

Person responsible for updating data

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
Street address
Massih Daneshvari Hospital, Daar-Abad, Niavaran, Tehran, Iran.
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Province
Tehran
Postal code
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+98 21 2712 2607
Email
mitra.safa@yahoo.com

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