Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The effect of combined regimen of ivermectin and fluoxetine on the prevention of hospitalization and amelioration of symptoms in mild covid-19 patients

Protocol summary

Study aim

Determining the effect of a combined treatment regimen of fluoxetine and ivermectin on the prevention of hospitalization and improvement of symptoms of mild covid-19 patients Providing an available and practical treatment to prevent exacerbation of symptoms and hospitalization in mild covid-19 patients

Design

This study will be conducted in parallel with the control group, in a three-way blind and randomized manner. Patients will be randomly divided into four groups, which will include 1 control group and three intervention groups that will receive combinations of ivermectin and fluoxetine.

Settings and conduct

This project will be carried out on eligible patients who refer to Fasa clinics and hospitals and are diagnosed with mild severity of Covid-19. None of the patients, caregivers, researchers, and analysts will have any information on how patients are assigned to groups or the use of drugs. In addition to the beginning of the study, the patient's symptoms will be followed daily until the end of the study and the results will be reported based on statistical analysis.

Participants/Inclusion and exclusion criteria

Patients have a definite diagnosis of Covid-19 and the severity of symptoms is mild. Currently, they do not have confounders such as the use of therapeutic drugs, special health conditions, or special chronic diseases.

Intervention groups

1- Control group will receive standard treatment. 2- Ivermectin group, in addition to the standard treatment, will receive daily doses of ivermectin based on weight range (48-50 kg, 9 mg; 51-80 kg, 12 mg; and >80 kg, 0.2 mg/kg) 3- Fluoxetine group, in addition to the standard treatment, will receive 20mg daily. 4- ivermectin + fluoxetine group, in addition to the standard treatment, will receive 20 mg fluoxetine daily and ivermectin like group 2.

Main outcome variables

hospitalization and development of symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220827055798N1**
Registration date: **2022-10-07, 1401/07/15**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-07, 1401/07/15**
Update count: **0**

Registration date

2022-10-07, 1401/07/15

Registrant information

Name

Majid Damiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3732 9646

Email address

farideaasadi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-01-20, 1401/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of combined regimen of ivermectin and fluoxetine on the prevention of hospitalization and amelioration of symptoms in mild covid-19 patients

Public title

The effect of ivermectin and fluoxetine on the amelioration of mild covid-19 patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

positive covid-19 PCR Completion of the informed consent questionnaire

Exclusion criteria:

Taking any SSRI for 10 days before the onset of clinical symptoms and going to the clinic History of mental illnesses Inability or unwillingness to continue studying The need for oxygen therapy or a history of home oxygen therapy History of chronic kidney and liver diseases Use of warfarin, ACE inhibitor, angiotensin II receptor antagonists Acquired immune system deficiency diseases Pregnancy or breastfeeding9- Malnutrition diseases Use of macrocyclic lactone drug family Use of ivermectin for 7 days before the symptoms of covid-19 Dialysis Participants who have participated in another trial study in the last six months.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **144**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are assigned to four treatment groups A, B, C, and D using Balance block randomization in an online source, https://www.randomizer.org/. the size of each block is 9 and the total number of blocks is 16. The balanced randomization allocation method will be used for the participants in the randomized controlled clinical trial study to investigate the effect of ivermectin (group A), fluvoxamine (group B), the combination of ivermectin and fluvoxamine (group C), and placebo (group D).

Blinding (investigator's opinion)

Triple blinded

Blinding description

Capsules containing the original drug and placebo (similar in appearance, smell, and taste to the original drug) are blinded only with completely random coding that only the person responsible for data protection and grouping is aware of. In this way, none of the people who participate in the study, the project researchers, and those who are communicating and evaluating the patients will know how to allocate groups and drugs. Finally, for analysis, the groups are only numbered based on numbers, which are only available to the data protection officer. The analyst does not know which of the studied groups will be the intervention and which will be the witnesses.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Fasa university of medical science ethics committee

Street address

Ebn Sina square

City

Fasa

Province

Fars

Postal code

7157847513

Approval date

2022-08-24, 1401/06/02

Ethics committee reference number

IR.FUMS.REC.1401.074

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

J06

ICD-10 code description

Acute upper respiratory infections of multiple and unspecified sites

Primary outcomes

1

Description

hospitalization

Timepoint
before the start of the study and 5 days after the start of the study
Method of measurement
questionnaire

2

Description
development of symptoms
Timepoint
before the start of the study and 5 days after the start of the study
Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Ivermectin group: in this group, in addition to the standard treatment, participants in this group will receive daily doses of ivermectin according to their weight range (48 to 50 kg, 9 mg; 51 to 80 kg, 12 mg; and >80 kg, 0.2 mg/kg)
Category
Treatment - Drugs

2

Description
Fluoxetine intervention group: in this group, in addition to the standard treatment, the participants in this group will receive 20mg capsules daily.
Category
Treatment - Drugs

3

Description
ivermectin + fluoxetine intervention group: in this group, in addition to the standard treatment, the participants in this group will receive 20 mg of fluoxetine capsules daily and ivermectin (48 to 50 kg, 9 mg; 51 to 80 kg, 12 mg; and >80 kg, 0.2 mg/kg) daily
Category
Treatment - Drugs

4

Description
Control group: Participants in this group will receive only standard treatment according to the guidelines of the Ministry of Health.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fasa hospitals and clinics
Full name of responsible person
Majid Damiri
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Fasa University of Medical Sciences
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Grant name
This research has been approved by Fasa University of Medical Sciences with the code of ethics IR.FUMS.REC.1401.074 and the research assistant will be the party to the contract to pay the approved financial costs in the project.
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Fasa 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
Fasa University of Medical Sciences
Full name of responsible person
Majid Damiri
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resident of the medical campus
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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
Yes - There is a plan to make this available
Title and more details about the data/document
The study will be uploaded as a protocol and preprint
When the data will become available and for how long
at the end of the statistical analysis
To whom data/document is available
Judicial officers and licensed researchers
Under which criteria data/document could be used
People who intend to conduct research in an official voice and according to international conventions have received an official letter of cooperation from the ethics committee center.
From where data/document is obtainable
academic email
What processes are involved for a request to access data/document
Refer to the ethics committee and obtain the necessary permission to provide data
Comments