

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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

Street address

Ebn sina square

City

fasa

Province

Fars

Postal code

7157847513

Phone

+98 917 716 1846

Email

farideaasadi@gmail.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Fasa University of Medical Sciences

Full name of responsible person

Yaser Mansori

Street address

Ebn Sina square

City

Fasa

Province

Fars

Postal code

7157847513

Phone

+98 917 132 5240

Email

fums.mansoori@gmail.com

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

Position

resident of the medical campus

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Ebn Sina square

City

Fasa

Province

Fars

Postal code

7157847513

Phone

+98 71 5335 0994

Email

fahimeasadi@gmail.com

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

Fasa University of Medical Sciences

Full name of responsible person

Majid Damiri

Position

internist resident of medical campus

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Ebn Sina square

City

Fasa

Province

Fars

Postal code

7157847513

Phone

+98 71 5335 0994

Email

fahimeasadi@gmail.com

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

Fasa University of Medical Sciences

Full name of responsible person

Majid Damiri

Position

internist resident of medical campus

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Ebn Sina square

City

Fasa

Province

Fars

Postal code

7157847513

Phone

+98 71 5335 0994

Email

fahimeasadi@gmail.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

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