

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the Effects of Sertraline on the Prognosis of Patients with Covid - 19 Admitted to Hospital

Protocol summary

Study aim

Determining the effect of Sertraline on the prognosis of patients with Covid-19 hospitalized

Design

Clinical trial study, one-blind, randomized, phase 3 on 60 patients, divided into two groups of intervention and control based on permutation block.

Settings and conduct

In this study, 60 patients who, due to their clinical condition, PCR and CT scan results, or physician's clinical diagnosis, needed to be hospitalized in Sabzevar Vasei Hospital, were divided into two groups, intervention & control, based on the inclusion criterias and permutation block. The treatment assignor and the evaluator of the desired outcomes do not know the type of drug used in each group. In the intervention group, sertraline was added to the patient's main drug regimen, while the control group received only the standard regimen.

Participants/Inclusion and exclusion criteria

1) Patients 18-65 years old with Covid-19 need hospitalization 2) Patient consent to participate in the study 3) Effective underlying diseases as a result of the study, whether previous cardiovascular or pulmonary diseases or other diseases and special conditions such as diabetes, weakened immune system and pregnancy 4) History of psychiatric illness or use of SSRIs including Sertraline

Intervention groups

In this study, patients are divided into two groups of intervention and control; Both groups will receive the main treatment regimen including corticosteroids + anticoagulants + Remdecivir, but in the intervention group Sertraline will be added to the treatment regimen group at 50 mgr / daily, but in the control group only the standard treatment will be used.

Main outcome variables

Evaluation of the effect of sertraline on the prognosis of patients with Covid-19

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220110053681N1**

Registration date: **2022-03-27, 1401/01/07**

Registration timing: **prospective**

Last update: **2022-03-27, 1401/01/07**

Update count: **0**

Registration date

2022-03-27, 1401/01/07

Registrant information

Name

Mahla sadat Esmaili

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 4465 1300

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-10-22, 1401/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effects of Sertraline on the Prognosis of Patients with Covid - 19 Admitted to Hospital

Public title

Effect of Sertraline in treatment of Covid-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients 18-65 years old with Covid-19 need to be hospitalized Patient consent to participate in the study

Exclusion criteria:

Effective underlying diseases as a result of the study, whether previous cardiovascular or pulmonary diseases or other diseases and special conditions such as diabetes, weakened immune system and pregnancy History of psychiatric illness or previous use of SSRIs including Sertraline

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

This project, which is actually a clinical trial, aims to investigate the effects of sertraline on the prognosis of patients with Covid-19, which requires hospitalization depending on the patient's clinical condition, PCR and CT scan results, or clinical diagnosis. In the hospital, patients are divided into intervention and control groups based on permutation block.

Blinding (investigator's opinion)

Single blinded

Blinding description

Because the patient is not asked to evaluate the consequences of the plan and is judged based on the patient's clinical examinations, patient blindness is not required. Only the evaluator of the results should be blindfolded. To do this, another person is used who is unfamiliar with the treatment process and the type of treatment received by the two groups

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Sabzevar University of Medical Sciences

Street address

Vasei hospital , Shohadaye Hasteii Blvd , Sabzevar

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617747431

Approval date

2022-01-04, 1400/10/14

Ethics committee reference number

IR.MEDSAB.REC.1400.139

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**

Duration of hospitalization

Timepoint

Daily, during the hospitalization period

Method of measurement

Patient clinical information collection form

2**Description**

Requires ICU care

Timepoint

Daily, during the hospitalization period

Method of measurement

Patient clinical information collection form

3**Description**

Oxygen Saturation

Timepoint

Daily, during the hospitalization period

Method of measurement

Patient clinical information collection form

4

Description

Respiratory rate

Timepoint

Daily, during the hospitalization period

Method of measurement

Patient clinical information collection form

5

Description

Type of oxygen therapy

Timepoint

Daily, during the hospitalization period

Method of measurement

Patient clinical information collection form

6

Description

Death

Timepoint

Daily, during the hospitalization period

Method of measurement

Patient clinical information collection form

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group receives 50 mg daily dose of sertraline with standard treatment including corticosteroids + anticoagulants + Remdesivir during hospitalization.

Category

Treatment - Drugs

2

Description

Control group: This group receives the main treatment regimen during the hospital stay, which includes corticosteroids + anticoagulants + Remdesivir .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Vasei hospital

Full name of responsible person

Houman Kamranian

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Vasei hospital , Shohadaye Hasteii Blvd , Sabzevar

,Razavi Khorasan Province, Iran

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waseehospital@medsab.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research and Technology of

Sabzevar University of Medical Sciences

Street address

Sabzevar University of Medical Sciences, above the Memorial of the Shohadaye Gomnam, Shohadaye Hastei Boulevard, Sabzevar

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Sabzevar University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Persons

Person responsible for general inquiries

Contact**Name of organization / entity**

Sabzevar University of Medical Sciences

Full name of responsible person

Mahla sadat Esmaeili

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

Others

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

Sabzevar University of Medical Sciences

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Houman Kamranian

Position

Assistant Professor

Latest degree

Specialist

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Full name of responsible person

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Position

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Other areas of specialty/work

Others

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available