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 Esmaeili
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 4465 1300
Email address
esmaeilim95@medsab.ac.ir

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
Street address
Vasei hospital , Shohadaye Hasteii Blvd , Sabzevar ,Razavi Khorasan Province, Iran
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617747431
Phone
+98 51 4465 1300
Email
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
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617913114
Phone
+98 51 4401 8101
Fax
+98 51 4401 8102
Email
vc.Research@medsab.ac.ir
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
Street address
Vasei hospital , Shohadaye Hasteii Blvd , Sabzevar ,Razavi Khorasan Province, Iran
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617747431
Phone
+98 51 4465 1300
Fax
+98 51 4465 3861
Email
esmaeilim95@medsab.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Sabzevar University of Medical Sciences
Full name of responsible person
Houman Kamranian
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
Vasei hospital , Shohadaye Hasteii Blvd , Sabzevar ,Razavi Khorasan Province, Iran
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617747431
Phone
+98 51 4465 1300
Email
drkamranian@yahoo.com

Person responsible for updating data

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
Street address
Vasei hospital , Shohadaye Hasteii Blvd , Sabzevar ,Razavi Khorasan Province, Iran
City
Sabzevar
Province
Razavi Khorasan
Postal code
9617747431
Phone
+98 51 4465 1300
Fax
+98 51 4465 3861
Email
esmaeilim95@medsab.ac.ir

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