Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Investigation of the Effectiveness of Ivermectin on Outpatient Treatment of Covid-19 Patients, Shiraz City, Southern Iran, 2020: A Randomized Controlled Trial Study (RCT)

Protocol summary

Study aim

Investigation of the Effectiveness of Ivermectin in Covid Positive Patients Referred to Selected Outpatient Treatment Centers in Shiraz

Design

Study participants are divided into three groups, including; 1) Single-dose intervention group 2) Double-dose intervention group 3) Control group: receiving placebo, n = 125 patients were calculated for each of the groups included in the study. In each group, patients are stratified according to age and blood oxygen level. Phase 3 studies are considered and the dice throwing function and Excel software are used for randomization.

Settings and conduct

The study was performed in selected outpatient treatment centers of Covid-19 in Shiraz among patients who have mild clinical manifestations, using a randomized trial method with a control group by stratification method and double-blind. Health care providers and study participants will be completely unaware of the type of drug treatment intervention method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Clients to selected outpatient treatment centers in Shiraz, which have only mild symptoms and clinical manifestations of Covid-19 disease in the age group of 18 to 80 years. Exclusion criteria: Patients with severe clinical signs and symptoms of Covid-19, patients with HIV, patients with severe disease; liver, kidney, lung, and with chronic obstructive pulmonary disease (COPD).

Intervention groups

Group 1, Single dose; (4 tab ivermectin on the first day) Group 2, Double dose; (4 tab ivermectin on the first and second day) Group 3, Placebo dose; (4 tab ivermectin on the first day)

Main outcome variables

Clinical manifestations, need for hospitalization, length of hospital stay, need for oxygen therapy, need to done intubation, and death

General information

Reason for update

Acronym

SHIE

IRCT registration information

IRCT registration number: **IRCT20210213050344N1**
Registration date: **2021-04-06, 1400/01/17**
Registration timing: **prospective**

Last update: **2021-04-06, 1400/01/17**
Update count: **0**

Registration date

2021-04-06, 1400/01/17

Registrant information

Name

Ali Semati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 5410

Email address

semati.epid77@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-10, 1400/01/21

Expected recruitment end date

2021-05-11, 1400/02/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the Effectiveness of Ivermectin on Outpatient Treatment of Covid-19 Patients, Shiraz City, Southern Iran, 2020: A Randomized Controlled Trial Study (RCT)

Public title

Effectiveness of Ivermectin on Outpatient Treatment of Covid-19 Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Clients to selected outpatient treatment centers in Shiraz Only mild symptoms and clinical manifestations (including: fever less than 38 degrees, sore throat with or without dry cough, chills, headache, loss of taste and smell, nausea, vomiting, anorexia, diarrhea, body aches, weakness and Excessive fatigue, persistent yard symptoms) Positive RT-PCR test result Age between 18 and 80 years People with underlying disease (to evaluate the effectiveness of the drug on people with underlying disease) Individuals who have completed and signed the written consent to participate in the project Blood oxygen level 93% and above (O2 sat ≥ 93%)

Exclusion criteria:

Pregnant mothers Breastfeeding mothers Severe liver disease Severe kidney disease Severe lung disease HIV Positive patients Chronic obstructive pulmonary disease (COPD) Participate in another RCT Dissatisfaction with participating in the study

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **375**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a Randomized Controlled Trial (RCT) study, with double-blind method and stratified random allocation, is defined for two intervention groups receiving Ivermectin (single dose and double dose) and control group (receiving placebo). Randomization is defined as blocking, person-centered, and stratified random layers. Prior to random allocation, due to the presence of two important factors in the prognosis of the disease, one is age and the other is the severity of the disease, study participants are placed in two age stratify under 55 years and above or equal to 55 years. Then, in each age group, they are divided into two other stratify in terms of disease severity; severe (O2 sat between 93 to 95%) and non-severe (O2 sat above 95%). After determining these four stratify, in each strata, random allocation with Permuted Block Random Allocation will be used to prevent inequality (Imbalance) in number of two intervention groups (single dose and double dose) and a control group (placebo) The blocks are in the form of three therapies (single dose, double dose and placebo) and three rooms. At each stage when a new block is selected, we randomly select one of the 6 blocks by rolling the dice. 1 A B C 2 A C B 3 B A C 4 B C A 5 C A B 6 C B A Single-dose intervention of Ivermectin is marked with (A) Intervention of two doses of Ivermectin is marked with (B) The control group (placebo) is marked with (C) Drug allocation interventions are unknown to the patient and therapist (allocation concealment). The order of administration of the drug to patients by another person, preferably by an epidemiologist.

Blinding (investigator's opinion)

Double blinded

Blinding description

Using a Randomized Controlled Trial (RCT) study, with double-blind method, Ivermectin and placebo, which are the same in shape, color, size and number, are labeled in similar packages with the letters B, A and C. According to the researcher's design, labeled drug packages are assigned to patients by physicians and health care providers of selected Covid-19 outpatient treatment centers. Therefore, none of the service providers and patients will be aware of the type of drug prescribed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand St., In front of Palestine St., The central building of Shiraz University of Medical Sciences, Shiraz

City

Shiraz

Province

Fars

Postal code

۱۴۳۳۶ - ۷۱۳۴۸

Approval date

2021-02-07, 1399/11/19

Ethics committee reference number
IR.SUMS.REC.1399.1202

Health conditions studied

1

Description of health condition studied
Covid-19 disease
ICD-10 code
U07.1
ICD-10 code description
Covid-19

Primary outcomes

1

Description
The trend of clinical symptoms of Covid-19 disease
Timepoint
Seven time periods on days: Zero, 1, 3, 7, 14, 21 and 28
Method of measurement
Clinical information by completing a qualitative questionnaire and conduct interviews and observations

2

Description
Blood oxygen level (O2 Saturation)
Timepoint
Seven Time Periods on Days: Zero, 1, 3, 7, 14, 21 and 28
Method of measurement
Pulse oximeter device

3

Description
Hospitalization
Timepoint
Seven time periods on days: Zero, 1, 3, 7, 14, 21 and 28
Method of measurement
Clinical information by completing a qualitative questionnaire and observation

4

Description
Requires intubation or ICU
Timepoint
Seven time periods on days: Zero, 1, 3, 7, 14, 21 and 28
Method of measurement
Clinical information by completing a qualitative questionnaire and observation

5

Description
Death
Timepoint
Seven time periods on days: Zero, 1, 3, 7, 14, 21 and 28
Method of measurement
Clinical information by completing a qualitative questionnaire and observation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: As a single dose, receive 4 tablets of Ivermectin 3 mg on the first day of treatment. M.A. Holder: Jam Tadbir Kala / Tehran, Iran - Manufactured by: Europhartec / France
Category
Treatment - Drugs

2

Description
Intervention group 2: As a double dose, receiving 4 tablets of 3 mg Ivermectin on the first day and 4 tablets of 3 mg Ivermectin on the second day of treatment. M.A. Holder: Jam Tadbir Kala / Tehran, Iran - Manufactured by: Europhartec / France
Category
Treatment - Drugs

3

Description
Control group: Receiving 4 placebo tablets on the first day of treatment (made in the laboratory of combined drugs of Shiraz School of Pharmacy)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemeh Zahra outpatient treatment center
Full name of responsible person
Dr. Mostafa Ebrahimi
Street address
South Hemmat Ave, Moallem Square
City
Shiraz
Province
Fars
Postal code
۱۴۳۳۶ - ۷۱۳۴۸
Phone
+98 71 3212 7414
Email
ebrahimi.m.cdc@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Abdul Rasool Hemmati
Street address
Zand St., In front of Palestine St., The central building of Shiraz University of Medical Sciences, Shiraz
City
Shiraz
Province
Fars
Postal code
۱۴۳۳۶ - ۷۱۳۴۸
Phone
+98 71 3212 2368
Email
r.hemmati@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Ali Semati
Position
Msc in Epidemiology, Expert in charge of the technical Vice Chancellor of the University
Latest degree
Master
Other areas of specialty/work
Epidemiology
Street address
Zand St., In front of Palestine St., The central building of Shiraz University of Medical Sciences
City
Shiraz
Province
Fars
Postal code
۱۴۳۳۶ - ۷۱۳۴۸
Phone
+98 71 3212 2368
Email
semati.epid77@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr. Ali Reza Mirahmadizadeh
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Epidemiology
Street address
Zand St., In front of Palestine St., The central building of Shiraz University of Medical Sciences
City
Shiraz
Province
Fars
Postal code
۱۴۳۳۶ - ۷۱۳۴۸
Phone
+98 71 3212 2368
Email
reza13441@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Ali Semati
Position
Msc in Epidemiology, Expert in charge of technical Vice Chancellor of University Health
Latest degree
Master
Other areas of specialty/work
Epidemiology
Street address
Zand St., In front of Palestine St., The central building of Shiraz University of Medical Sciences
City
Shiraz
Province
Fars
Postal code
۱۴۳۳۶ - ۷۱۳۴۸
Phone
+98 71 3212 2368
Email
semati.epid77@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
Undecided - It is not yet known if there will be 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
1- Random allocation table 2- Patients stratification table based on prognostic factors of age and O2 saturation 3- Excel data table

When the data will become available and for how long
3 months after the publication of the final report / article

To whom data/document is available
People who work in infectious disease management, medical management, and reputable scientific and research centers

Under which criteria data/document could be used
In order to prepare results separate from the results obtained from this research and the relevant article, as well as conducting another analysis and research

From where data/document is obtainable
1- Via the postal address: Zand St., In front of Palestine St., The central building of Shiraz University of Medical Sciences. Postal code: 14336 - 71348 2- By sending an email to: semati.epid77@gmail.com 3-Through direct follow-up with Mr. Ali Semati, Expert in charge of technical deputy of Shiraz University of Medical Sciences (contact number: 09177131825- 07132122368)

What processes are involved for a request to access data/document
By conducting official correspondence with a numbered and stamped letter from a reputable scientific center / a university center, to the president or Vice Chancellor for Research of Shiraz University of Medical Sciences and after approval: Dean of the University / Vice Chancellor for Research of Shiraz University of Medical Sciences, Approval of the ethics committee and security of Shiraz University of Medical Sciences.

Comments
If the researcher intends to receive the data for a new research and analysis, through; 1- Concluding a memorandum / agreement with the Vice Chancellor for Health of Shiraz University of Medical Sciences 2- Full observance of the principles and standards of ethics in research 3- Personal data and information of individuals "only without disclosing important personal information" including; name, national number and ID number will be provided 4- Considering the intellectual rights of the research and development team of this research in Shiraz University of Medical Sciences