Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Dec 2021

Evaluation of the effect of oral Ivermectin on the outcome of patients with COVID-19 and compare it with the effect of conucntional therapics in patients admitted to Ziaeian, Baharloo, Imam Khomeini in the spring and summer 2020

Protocol summary

Study aim

Considering that COVID-19 is associated with high morbidity and mortality and high public health costs, and given that 100% cure for this disease has not been found, we decided to use the drug Ivermectin, which had promising results in Invitro studies and add to the routine treatment approved by the Ministry of Health and evaluate its effectiveness compared to routine treatment alone.

Design

This study is a multi-central blind one-way clinical trial

Settings and conduct

Patients with COVID-19 who have been referred to Ziaian, Imam Khomeini and Baharloo hospitals, after examination by a physician and obtaining informed consent, are placed in one of two control or intervention groups without any information and then a medication regimen for them.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 130 patients aged 18 to 50 years old hospitalized in Ziaeian, Baharloo and Imam Khomeini Medical Centers proven cases of COVID-19 After obtaining informed written consent consciously, they are randomly divided into two groups.Exclusion criteria: Severely ill and hospitalized in the intensive care unit, patients who are unable to take oral medications, patients with AST / ALT levels more than 5 times above normal, and pregnant patients do not enter the study.

Intervention groups

Patients in the control group are treated with Hydroxychloroquine sulfate and Azithromycin (if there is no cardiac contraindication) according to the protocol of the Ministry of Health. In addition to these drugs, Ivermectin 200 mg (four 3mg tablets in a 60 kg person) is given to the intervention group on the first day and a 3mg tablet is administered every 12 hours for 3 days from the second day.

Main outcome variables

Improving clinical symptoms; reducing the length of hospitalization; improving paraclinical indicators of the disease; lack of response to treatment and hospitalization in the ICU

General information

Reason for update

Acronym

EIC

IRCT registration information

IRCT registration number: **IRCT20180922041089N4**
Registration date: **2020-08-23, 1399/06/02**
Registration timing: **retrospective**

Last update: **2020-08-23, 1399/06/02**
Update count: **0**

Registration date

2020-08-23, 1399/06/02

Registrant information

Name

Abolfazl Zendehdel

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5517 6031

Email address

azendedel@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2020-04-19, 1399/01/31
Expected recruitment end date
2020-08-19, 1399/05/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of oral Ivermectin on the outcome of patients with COVID-19 and compare it with the effect of conucntional therapics in patients admitted to Ziaeian, Baharloo, Imam Khomeini in the spring and summer 2020

Public title
Evaluation of the effect of oral Ivermectin on patients with COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients 18 to 50 years Infected by the COVID 19 virus Patients with clinical symptoms, history of exposure to the patient and a positive RT-PCR test for Covid 19 from A laboratory or characteristic signs on a CT scan of the chest) with mild to moderate clinical manifestations according to the National Early Warning Score (NEWS) (mild: 1-4 / moderate: 5-6) Obtaining informed written consent consciously
Exclusion criteria:
Severely ill and hospitalized in the intensive care unit Patients who are unable to take oral medications Patients with AST / ALT levels more than 5 times above normal Pregnant patients
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **130**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into two groups using the black box randomization method (simple). First, patients are selected based on inclusion and exclusion criteria by the treating physician. And then are introduced to the research expert for randomization assignment. Out of 130 patients, he randomly placed 65 people in the intervention group in red and 65 people in the control group in green and informed the therapist. Patients do not know which group they are in.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients in this study are blind who enter the study after obtaining informed consent without knowing what group they are in.
Placebo
Not used
Assignment
Parallel
Other design features
This study is a multi-central blind one-way clinical trial. A total of 130 patients aged 18 to 50 years admitted to Ziaeian, Baharloo and Imam Khomeini Educational and Medical Centers have been shown to have Covid 19 with mild to moderate clinical manifestations. According to NEWS (mild score 1-4, average score 5-6), after obtaining written consent consciously, they are randomly divided into two groups. The person in charge of collecting patient information during admission and after evaluating drug treatments is unaware of which of the intervention or control groups the patient is in.The control group consisted of 65 patients who were treated with Hydroxychloroquine and azithromycin and the intervention group consisted of 65 patients who, in addition to the above-mentioned regimen, Ivermectin was added to the treatment protocol.This study is part of the phase 3 studies or the classic clinical trial studies.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran National Committee For Ethics in Biomedical Research
Street address
13th floor, Block A, Central Headquarters of the Ministry of Health, Treatment and Medical Education, Between South Flamek and Zarafshan St., Shahrak Ghods
City
Tehran
Province
Tehran
Postal code
1366736511
Approval date
2020-04-29, 1399/02/10
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1399.031

Health conditions studied

1

Description of health condition studied
Corona virus

ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Improving clinical symptoms
Timepoint
Daily
Method of measurement
National Early Warning Score، (NEWS)

2

Description
Reducing the length of hospitalization
Timepoint
Daily
Method of measurement
Counting

3

Description
Improving paraclinical indicators of the disease
Timepoint
Daily lymphocyte count - the last day of hospital CT scan
Method of measurement
Lymphocyte count - CT scan

Secondary outcomes

1

Description
Lack of response to treatment and hospitalization in the ICU
Timepoint
Daily
Method of measurement
Assessing clinical manifestations

Intervention groups

1

Description
Control group: Patients in the control group are treated with Hydroxychloroquine sulfate and Azithromycin (if there is no cardiac contraindication) according to the protocol of the Ministry of Health
Category
Treatment - Drugs

2

Description
Intervention group: In the intervention group, in addition to medication Hydroxychloroquine sulfate and Azithromycin,Ivermectin 200 mg (four 3mg tablets in a 60 kg person) is given to the intervention group on the first day and a 3mg tablet is administered every 12 hours for 3 days from the second day.At the beginning of hospitalization NEWS of patients are checked and ECG is performed, and CBC diff test for lymphopenia, LFT, etc. (according to the ministry protocol) is also performed. Patients are compared after hospitalization for NEWS, clinical signs, and lymphocyte counts daily and CT scan is performed on the last day of hospitalization.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ziaeian Hospital
Full name of responsible person
Abolfazl Zendedel
Street address
Ziaian Hospital, Abuzar St,Tehran Town
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2

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Abolfazl Zendedel
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End of Keshavarz Boulevard, Dr. Gharib Street
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3

Recruitment center
Name of recruitment center
Baharloo Hospital
Full name of responsible person

Saeedreza Jamali moghadam

Street address
Railway Square - Behdari Street - Baharloo Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Mohammadali Sahraeeian

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Keshavarz Blvd - Qods St, Tehran University of Medical Sciences

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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
There was no financial backer

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
Tehran University of Medical Sciences

Full name of responsible person
Abolfazl Zendehdel

Position
Ziaian Hospital Education Assistant

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

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Abolfazl Zendehdel

Position
Ziaian Hospital Education Assistant

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Abolfazl Zendehdel

Position
Ziaian Hospital Education Assistant

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

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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