Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A randomized clinical trial study, comparison of the therapeutic effects of Ivermectin, Kaletra and Chloroquine with Kaletra and Chloroquine in the treatment of patients with coronavirus 2019 (COVID-19)

Protocol summary

Study aim
Clinical trial study of the therapeutic effect of Ivermectin in combination with Kaletra and Chloroquine diet in the treatment of Coronavirus patients in 2019 (COVID-19)

Design
Clinical trial with control group, parallel group trial, double-blinded, phase 2 on 60 patients. Replacement randomization was used.

Settings and conduct
In both study groups (control and case), on the first day, patients will receive chloroquine at a dose of 200 mg, and from the second day for six consecutive days they will receive Lopinavir / ritonavir (Kaletra) at a dose of 400/100 mg. At the first day, in addition to the above drugs, Ivermectin 200–150 µg/kg, is given.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. People over 18 years of age. 2. Positive Real-time PCR test for SARS-CoV-2 virus positive after sampling (nasopharyngeal and oropharyngeal swab samples). 3. Pneumonic manifestations of the virus. In CT scans of the lungs, they should be clearly visible, with a 4% lower O2 Saturation of 93% exclusion criteria: 1- History of renal failure, 2- Taking drugs that interfere with Ivermectin and 3- Patients who have been included in other clinical trial studies

Intervention groups
Case group: Get the Ivermectin plus Kaletra plus Chloroquine Control group: Get the Kaletra plus Chloroquine

Main outcome variables
Reduce the length of admission time, Reduce the length of ICU admission time, preventing the progression of the disease to acute respiratory distress syndrome (ARDS), Reducing fever, increasing oxygen saturation, Reducing dyspnea, Reducing Respiratory rate, Decreased heart rate.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200422047168N2**
Registration date: **2020-05-30, 1399/03/10**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-30, 1399/03/10**
Update count: **0**

Registration date
2020-05-30, 1399/03/10

Registrant information

Name
Zahra Shokati

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 61 3333 5678

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-30, 1399/03/10

Expected recruitment end date
2020-07-20, 1399/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A randomized clinical trial study, comparison of the therapeutic effects of Ivermectin, Kaletra and Chloroquine with Kaletra and Chloroquine in the treatment of patients with coronavirus 2019 (COVID-19)

Public title
Clinical trial study of the therapeutic effect of Ivermectin, besides Kaletra and Chloroquinein in patients with Coronavirus disease 2019 (COVID-19)

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People over 18 years old Real-time PCR test results for SARS-CoV-2 virus were positive after sampling (nasopharynx and oropharynx swab samples) The manifestations of virus pneumonia in CT scans of their lungs were quite obvious. Their O2 Saturation percentage were 93% or lower

Exclusion criteria:
History of renal failure Taking drugs that interfere with Ivermectin Patients who have been admitted to other clinical trials

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we will use the Restricted randomization method of block randomization. Blockage is usually used to balance the number of samples allocated to each of the studied groups. This feature helps researchers to equalize the number of samples allocated to each of the studied groups in cases where intermediate analyzes are required during the sampling process. All blocks are the same size, and in this two-group experiment we will have 6 blocks (including 3 participants in the intervention group and 3 participants in the control group). Random allocation software is also used to randomize random sequence production software (Random allocation software). To conceal, we use Allocation concealment, which refers to the method used to perform a random sequence on study participants, so that the assigned group is not identified before the individual is assigned. Using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). In this method, each of the random sequences created is recorded on a card and the cards are placed in the letter envelopes in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.

Blinding (investigator's opinion)
Single blinded

Blinding description
To reduce bias, the single-blinded method is used, which can be sure the outcome was measured objectively. In this method, the participant does not know which of the two groups of control or test belongs.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Jundishapur University of Medical Sciences

Street address
Alimentary Tract Research Center, Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran

City
Ahvaz

Province
Khouzestan

Postal code
6163837194

Approval date
2020-05-27, 1399/03/07

Ethics committee reference number
IR.AJUMS.REC.1399.194

Health conditions studied

1

Description of health condition studied
covid-19

ICD-10 code
U07.1

ICD-10 code description
Covid-19, confirmed cases, positive test result

Primary outcomes

1

Description
Reduce the mortality rate of patients with Covid-19

Timepoint

days 0-7

Method of measurement

Based on the percentage of discharged Covid-19 patients

Secondary outcomes

1

Description

Treatment period

Timepoint

0-7

Method of measurement

Based on the days numbers of the drug usage

2

Description

Duration of infection

Timepoint

0-7

Method of measurement

Based on the patient's clinical symptoms

3

Description

Duration of admission time

Timepoint

0-7

Method of measurement

Number of admission days due to Covid-19

4

Description

Duration of ICU admission time

Timepoint

0-7

Method of measurement

Number of ICU admission days due to Covid-19

5

Description

fever

Timepoint

0-7

Method of measurement

Rising body temperature

6

Description

Blood oxygen saturation percentage

Timepoint

0-7

Method of measurement

O2 saturation percentage

7

Description

Respiratory rate

Timepoint

0-7

Method of measurement

respiratory rate per minute

8

Description

heart rate

Timepoint

0-7

Method of measurement

heart rate per minute

9

Description

Discharge situation

Timepoint

0-7

Method of measurement

Alive or dead

10

Description

Use non-invasive respiratory methods

Timepoint

0-7

Method of measurement

Patients percentage that be supported by non-invasive breathing methods

11

Description

Use invasive respiratory methods

Timepoint

0-7

Method of measurement

Patients percentage that be supported by invasive breathing methods

Intervention groups

1

Description

Intervention group: On the first day, patients will receive chloroquine at a dose of 200 mg, and from the second day for six consecutive days, they will receive Lopinavir / ritonavir (Kaletra) at a dose of 400/100 mg. At the first day,in addition to the above drugs,Ivermectin, 200–150 μg/kg، is given.

Category

Treatment - Drugs

2

Description

Control group: On the first day, patients will receive chloroquine at a dose of 200 mg, and from the second

day for six consecutive days, they will receive Lopinavir / ritonavir (Kaletra) at a dose of 400/100 mg.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Razi hospital

Full name of responsible person

Ali akbar Shayesteh

Street address

Alimentary Tract Research Center-- Imam Khomeini Hospital - Ahvaz- Khuzestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Ahvaz University of Medical Sciences

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Adult Gastroenterology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Zahra Shokati

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Molecular medicine

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Latest degree
Ph.D.

Other areas of specialty/work
Molecular medicine

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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