Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 2026

Determination the therapeutic effect of Ivermectin and Sovodak on patients infected with COVID-19: A clinical trial.

Protocol summary

Study aim

purpose of this study is to Determine the therapeutic effect of Ivermectin and Sovodak on patients infected with COVID-19.

Design

clinical trial with control group, with parallel groups (5 groups in sum), double blinded, randomized with Randomizer software, with 150 participants.

Settings and conduct

This randomized double blinded clinical trial will be implemented in Qazvin Bu Ali hospital.

Participants/Inclusion and exclusion criteria

1. Patients who test positive for COVID-19 by a commercially available Rapid Antigen Test (RAT) of the nasopharynx. 2. Patients ≥ 20 but < 65 years of age with a temperature (oral) of 100.4°F (38.0°C) or more; patients ≥ 65 years of age with a temperature (oral) of 100.0°F (37.8°C) or more at the first visit, or in the 6 hours prior if antipyretics were taken. 3. Patients with 2 or more of the following symptoms (moderate to severe in intensity) at the time of enrollment: o Cough o Sore throat o Headache o Nasal congestion o Feeling feverish o Body aches o Fatigue

Intervention groups

Control group 1: Standard regimen based on Iran health ministry, Control group 2: Standard regimen based on Iran health ministry plus Placebo, Intervention group 1: Standard regimen based on Iran health ministry plus Ivermectin (400 mcg/kg , PO, Once) and Sovodak(400/60, PO, Once), Intervention group 2: Standard regimen based on Iran health ministry plus high dose Ivermectin(400 mcg/kg in day1 followed by 200 mcg/kg in day 3 and day 5) and Sovodak(400/60, PO, Once), Intervention group 3: High dose Ivermectin (400 mcg/kg in day1 followed by 200 mcg/kg in day 3 and day 5) and Sovodak(400/60, PO, Once).

Main outcome variables

chest CT scan, hospitalization time, CBC and CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200408046987N2**
Registration date: **2020-11-07, 1399/08/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-07, 1399/08/17**
Update count: **0**

Registration date

2020-11-07, 1399/08/17

Registrant information

Name

Nematollah Gheibi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3332 8212

Email address

ngheibi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-16, 1399/07/25

Expected recruitment end date

2020-12-15, 1399/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination the therapeutic effect of Ivermectin and Sovodak on patients infected with COVID-19: A clinical trial.

Public title
Determination the therapeutic effect of Ivermectin and Sovodak on patients infected with COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who test positive for COVID-19 by a commercially available Test Patients ≥ 20 but < 65 years of age with a temperature (oral) of 38°C and patients 65 - 80 years of age with a temperature (oral) of 37.8°C Patients with 2 or more of the following symptoms (moderate to severe in intensity) at the time of enrollment: Cough Sore throat Headache Nasal congestion Feeling feverisho Body aches and pains Fatigue (tiredness)
Exclusion criteria:
patients with Immuno deficiency patients under any other antiviral therapy
Age
From **20 years** old to **80 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, simple randomization method will be used. A randomized list will be generated by Randomizer randomization software. Patients will be allocated to case or control group according to the generated list.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants will receive drug or placebo after signing the consort letter. Practitioner and consequence analyzer will not know about the treatment. Data analyzer will know the groups number only.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Qazvin university of medical sciences
Street address
Bahonar Boulevard
City
Qazvin
Province
Qazvin
Postal code
3419915315
Approval date
2020-09-20, 1399/06/30
Ethics committee reference number
IR.QUMS.REC.1399.228

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
Chest image(CT scan)
Timepoint
at hospital clearance
Method of measurement
Patient's profile(CT scan image)

2

Description
hospitalization time
Timepoint
end of intervention
Method of measurement
Hospitalization time

3

Description
CBC
Timepoint
Before intervention, 7 days after intervention
Method of measurement
Sampling and lab test

4

Description
CRP
Timepoint
Before intervention, 7 days after intervention
Method of measurement
Sampling and lab test

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Standard regimen based on Iran health ministry
Category
Treatment - Drugs

2

Description
Control group: Standard regimen based on Iran health ministry plus Placebo,Once in first day. placebo is a simple tablet containing only fillers without any active ingredient and is made by Alborz Darou company.
Category
Treatment - Drugs

3

Description
Intervention group: Standard regimen based on Iran health ministry plus Ivermectin (400 mcg/kg , PO, Once) and Sovodak(400/60, PO, Once)
Category
Treatment - Drugs

4

Description
Intervention group: Standard regimen based on Iran health ministry plus high dose Ivermectin(400 mcg/kg in day1 followed by 200 mcg/kg in day 3 and day 5) and Sovodak(400/60, PO, Once)
Category
Treatment - Drugs

5

Description
Intervention group: High dose Ivermectin (400 mcg/kg in day1 followed by 200 mcg/kg in day 3 and day 5) and Sovodak(400/60, PO, Once)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bu Ali hospital
Full name of responsible person
Dr. Aliakbar Karami, Dr Elham Zsabganeh
Street address
velayat hospital, taavon square, 22 bahman boulevard, Minoodar town
City
Qazvin
Province
Qazvin
Postal code
3471991984
Phone
+98 28 3379 0620
Email
Ali32024@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Akam Tejarat Fartak Farasoo
Full name of responsible person
Morteza Shakhs Niaee
Street address
Nokhbegan Boulevard, Qazvin science and technology park
City
Qazvin
Province
Qazvin
Postal code
3471991984
Phone
+98 28 3336 7100
Email
dr.niaee@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Akam Tejarat Fartak Farasoo
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
Qazvin University of Medical Sciences
Full name of responsible person
Nematollah Gheibi
Position
professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Biotechnology
Street address
Bahonar Boulevard
City
Qazvin
Province
Qazvin
Postal code
3741999184
Phone
+98 28 3332 8212
Email
ngheibi@qums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Nematollah Gheibi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Biotechnology
Street address
Bahonar Boulevard
City
Qazvin
Province
Qazvin
Postal code
3741999184
Phone
+98 28 3332 8212
Email
ngheibi@qums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Nematollah Gheibi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Biotechnology
Street address
Bahonar Boulevard
City
Qazvin
Province
Qazvin
Postal code
3741999184
Phone
+98 28 3332 8212
Email
ngheibi@qums.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