

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 May 2021

Evaluation of prophylaxis induced by ivermectin in populations exposed to COVID-19 patients

Protocol summary

Study aim

Evaluation of prophylaxis induced by ivermectin in populations exposed to COVID-19 patients to provide a safe and low-cost way to cure or lowering the consequences of COVID-19

Design

Phase 3 Clinical trial with control group, with parallel groups(4 groups), double blinded, randomized with Randomizer software, with 800 participants.

Settings and conduct

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

Participants/Inclusion and exclusion criteria

Inclusion: Healthy individuals exposed directly and constantly with COVID-19 patients. COVID-19 patients who their disease is confirmed by RT-PCR test and low to moderate severity(Grade<3); Patients with O2 saturation>94 who fit outpatient protocol; Having consent for participating in study Exclusion: Pregnant or breastfeeding women; individuals with a certain CNS disease Individuals with an uncontrolled disease(Asthma, COPD, cardiovascular disease, diabetes, Kidney or Liver dysfunction, Cancer, Hepatitis, AIDS, Immunodeficiency); Patients receiving immuno suppressive drugs individuals receiving any P-450 or P-gp blockers or any medication interacting with ivermectin; patients under antiviral therapy individuals receiving any Corticosteroid(Inhaling, PO or Injection) any known sensitivity to Ivermectin or starch or history of lactose intolerability(for Placebo); individuals with positive SARS-CoV-2 specific antibody

Intervention groups

Group 1: Ivermectin to patient and Placebo to other members of family Group 2: Ivermectin to other members of family and Placebo to patient Group 3: Ivermectin to patient and other members of family Group 4: Placebo to patient and other members of family

Main outcome variables

Mean of Viral load of patients in days 0,4,7,14,21,28
Considering disease progress in days 0,4,7,14,21,28

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200408046987N3**

Registration date: **2020-12-06, 1399/09/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-06, 1399/09/16**

Update count: **0**

Registration date

2020-12-06, 1399/09/16

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

2020-11-30, 1399/09/10

Expected recruitment end date

2020-12-30, 1399/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of prophylaxis induced by ivermectin in populations exposed to COVID-19 patients

Public title

Evaluation of prophylaxis induced by ivermectin in populations exposed to COVID-19 patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Healthy individuals exposed directly and constantly with COVID-19 patients. COVID-19 patients whose disease is confirmed by RT-PCR test and low to moderate severity (Grade < 3). Patients with O₂ saturation > 94 who fit outpatient protocol. Having consent for participating in study

Exclusion criteria:

Pregnant or breastfeeding women individuals with a certain CNS disease Individuals with an uncontrolled disease (Asthma, COPD, cardiovascular disease, diabetes, Kidney or Liver dysfunction, Cancer, Hepatitis, AIDS, Immunodeficiency) Patients receiving immunosuppressive drugs individuals receiving any P-450 or P-gp blockers or any medication interacting with ivermectin patients under antiviral therapy individuals receiving any Corticosteroid (Inhaling, PO or Injection) any known sensitivity to Ivermectin or starch or history of lactose intolerance (for Placebo) individuals with positive SARS-CoV-2 specific antibody

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyst

Sample size

Target sample size: **800**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple randomization method will be used. A randomized list will be generated by online randomization site. Simple randomization will be generated with a computer from 1 to 800. The computer will divide the digits between the four groups. According to the sequences of admission, they will go to the control or the intervention group regarding the computerized random list.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will receive drug or placebo after signing the consent 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

2020-10-04, 1399/07/13

Ethics committee reference number

IR.QUMS.REC.1399.261

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

Percentage of patients in family members

Timepoint

The day of zero and 3 days after taking the drug, then every week for a month (until complete recovery of family members) days 0, 3, 7, 14, 21, 28

Method of measurement

Follow-up and questionnaire from the patient about the symptoms of the Covid 19

2

Description

Duration of illness

Timepoint

The day of zero and 3 days after taking the drug, then every week for a month (until complete recovery of family members) days 0, 3, 7, 14, 21, 28

Method of measurement

Follow-up and questionnaire from the patient about the symptoms of the Covid 19

3

Description

Severity of disease

Timepoint

The day of zero and 3 days after taking the drug, then every week for a month (until complete recovery of family members)days 0, 3, 7, 14, 21, 28

Method of measurement

Follow-up and questionnaire from the patient about the symptoms of the Covid 19

Secondary outcomes

1

Description

Considering the drug side effects during the study

Timepoint

3 days after taking the drug, then every week for a month (until complete recovery of family members)days 0, 3, 7, 14, 21, 28

Method of measurement

Follow-up and questionnaire from the patient about the symptoms of the Covid 19

2

Description

Considering the changes in serum antibody level of IgA

Timepoint

The day of zero and 3 days after taking the drug, then every week for a month (until complete recovery of family members)days 0, 3, 7, 14, 21, 28

Method of measurement

Serologic test-ELISA

3

Description

Considering the changes in serum antibody levels of IgM

Timepoint

The day of zero and 3 days after taking the drug, then every week for a month (until complete recovery of family members)days 0, 3, 7, 14, 21, 28

Method of measurement

Serologic test-ELISA

4

Description

Considering the changes in serum antibody levels of IgG

Timepoint

The day of zero and 3 days after taking the drug, then every week for a month (until complete recovery of family members)days 0, 3, 7, 14, 21, 28

Method of measurement

Serologic test-ELISA

5

Description

Duration of the illness with recheck of Rt-PCR at days

Timepoint

The day of 3 and 7 after taking the drug

Method of measurement

Rt-PCR test

Intervention groups

1

Description

Intervention group: : Ivermectin(200 mcg/Kg, PO, Once) to patient and Placebo(PO,Once) to other members of family

Category

Treatment - Drugs

2

Description

Intervention group: Ivermectin(200 mcg/Kg, PO, Once) to other members of family and Placebo(PO,Once) to patient

Category

Treatment - Drugs

3

Description

Intervention group: Ivermectin(200 mcg/Kg, PO, Once) to patient and other members of family

Category

Treatment - Drugs

4

Description

Control group: Placebo(PO, Once) to patient and other members of family, placebo is made by Alborz Darou company including all Ivermectin ingredients except active ingredient

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Hospital

Full name of responsible person

Abbas Allami

Street address

Bu ali street

City

Qazvin

Province

Qazvin

Postal code

3413786165

Phone

+98 28 3333 6001

Email

allami9@yahoo.com

2

Recruitment center

Name of recruitment center

Velayat Hospital

Full name of responsible person

fatemeh samieerad

Street address

Minoodar

City

Qazvin

Province

Qazvin

Postal code

Email

fsamieerad@gmail.com

3

Recruitment center

Name of recruitment center

Shahid Bolandian

Full name of responsible person

Alireza Mehralian

Street address

Daneshgah

City

Qazvin

Province

Qazvin

Postal code

Email

AlirezaMehralian@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Akam Tejarat Fartak Farasoo Company

Full name of responsible person

Morteza Shakhsi Niaee

Street address

Qazvin science & technology park

City

Qazvin

Province

Qazvin

Postal code

3471991984

Phone

+98 28 3336 7001

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 Company

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

Not applicable