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 andother 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 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 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 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
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

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

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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

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Person responsible for scientific inquiries

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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

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Person responsible for updating data

Contact
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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
Not applicable