Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Dec 2023

Evaluation effects of the standard regimen along with ivermectin on treatment of corona virus type 2 pneumonia

Protocol summary

Study aim
The evaluation of ivermectin effects on treatment coronavirus infections
Design
Fifty patients with a computerized software allocated to intervention and control group in a randomized parallel open-label phase 3 study
Settings and conduct
This is an open-label randomized trial using simple randomization taking place in Kermanshah city, Farabi hospital in patients with coronavirus type-2 pneumonia.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Positive Covid-19 infection patients who are older than 18 years. Less than 14 days elapsed from symptoms initiation. Exclusion criteria: Active liver disease Underlying hematological disease Seizures and encephalopathy Allergies to drugs Pregnancy Breastfeeding Patients who wont to participate in the study
Intervention groups
In the intervention group, patients receive 150 micrograms per kilogram of ivermectin per day based on their body weight for 7 days along with the standard of care treatments. In the control groups, patients receive the standard of care treatments according to the national guideline.
Main outcome variables
Clinical response, virological recovery, recovery time, arterial blood gas, mortality

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190624043993N2**
Registration date: **2020-07-12, 1399/04/22**
Registration timing: **prospective**
Last update: **2020-07-12, 1399/04/22**
Update count: **0**
Registration date
2020-07-12, 1399/04/22

Registrant information
Name
foroud shahbazi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-08-22, 1399/06/01
Expected recruitment end date
2021-02-19, 1399/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation effects of the standard regimen along with ivermectin on treatment of corona virus type 2 pneumonia

Public title
Evaluation of ivermectin effects on Covid-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Definite (clinical and positive PCR) Covid-19 disease Less than 48 hours have passed since the onset of symptoms
Exclusion criteria:
Underlying liver disease/hepatitis Underlying hematological disorders Seizures and encephalopathy Known allergies to ivermectin Pregnancy/lactation Patients who themselves or their legal guardians are reluctant to participate or continue clinical trials

Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients are randomly divided into two groups using a computer random number generator with a 1:1 allocation. odd numbers receive ivermectin and standard of care, and even numbers receive standard of care, only.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical commitee of kermanshah university of medical sciences
Street address
The vice-chancellor for research and technology, Beheshti Ave, Kermanshah,
City
Kermanshah
Province
Kermanshah
Postal code
6719851351
Approval date
2020-06-16, 1399/03/27
Ethics committee reference number
IR.KUMS.REC.1399.289

Health conditions studied

1

Description of health condition studied
Type-2 coronavirus pneumonia
ICD-10 code
U07.2
ICD-10 code description
Severe acute respiratory syndrome [SARS]

Primary outcomes

1

Description
Clinical response
Timepoint
Day 7 and 14 after study initiation
Method of measurement
Clinical- radiographic

Secondary outcomes

1

Description
Virological response
Timepoint
Day 7
Method of measurement
PCR

Intervention groups

1

Description
Intervention group: Patients will recieved ivermectin (150mcg/kg/day) along with the standard of care
Category
Treatment - Drugs

2

Description
Control group: Patients will received the standard of care according to the national guideline.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi hospital
Full name of responsible person
Maria Shirvani
Street address

Farabi Medical education center, Dolat-Abad Boulevard, Isar Square, Kermanshah, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr. Farid Najafi

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Behesti Blve, Vice chancellor for research and technology

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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
Kermanshah 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
Kermanshah University of Medical Sciences

Full name of responsible person
Foroud Shahbazi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

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Person responsible for updating data

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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