

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Oct 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 want 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

Country

Iran (Islamic Republic of)

Phone

+98 83 3426 6780

Email address

foroud08@gmail.com

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 committee 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 received 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.

City

Kermanshah

Province

Kermanshah

Postal code

988338264820

Phone

+98 83 8216 0700

Email

maria_shirvani@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Behesti Blve, Vice chancellor for research and
technology

City

Kermanshah

Province

Kermanshah

Postal code

083-38370541

Phone

+98 83 3838 4185

Email

farid_n32@yahoo.com

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

Street address

School of pharmacy, Parastar Blve, Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

1673-67145

Phone

+98 83 3426 6780

Email

Foroud08@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Maria Shirvani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

School of medicine, Parastar Blve, Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

1673-67145

Phone

21- 08334274618

Email

Maria.shirvani@kums.ac.ir

Person responsible for updating data

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

Street address

School of pharmacy, Parastar Blve, Kermanshah

City

Kermanshah

Province

Kermanshah

Postal code

1673-67145

Phone

+98 83 3426 6780

Email

Foroud08@gmail.com

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