

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Oct 2020

Study of the effectiveness of concomitant use of vitamin C, metformin, azithromycin and doxycycline on improving patients with COVID-19

Protocol summary

Study aim

Study of the effectiveness of concomitant use of vitamin C, metformin, azithromycin and doxycycline on improving patients with COVID-19

Design

This study is a non-blinded clinical trial. The study population will include all patients with coronavirus referring to Golestan hospital of Kermanshah. 40 eligible patients will be selected conveniently and randomly assigned to two intervention and control groups.

Settings and conduct

This study that will be conducted in the Golestan hospital of Kermanshah is a non-blinded one. At the beginning of the study, clinical information is recorded in a checklist daily and imaging findings of a patient with suspected pneumonia are recorded in a checklist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with coronavirus have mild to moderate viral infections diagnosed by an infectious disease specialist Exclusion criteria: Patients with severe lung involvement and severe respiratory symptoms; patients with G6PD deficiency

Intervention groups

The intervention group will receive 250 mg of azithromycin daily, 100 mg of doxycycline twice daily, 1.5 g of vitamin C every 6 hours, and 500 mg of metformin daily for one week.

Main outcome variables

Disease recovery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200418047121N1**

Registration date: **2020-05-01, 1399/02/12**

Registration timing: **prospective**

Last update: **2020-05-01, 1399/02/12**

Update count: **0**

Registration date

2020-05-01, 1399/02/12

Registrant information

Name

KAMRAN MANSOURI

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3427 6473

Email address

kmansouri@kums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2020-05-09, 1399/02/20

Expected recruitment end date

2020-12-10, 1399/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effectiveness of concomitant use of vitamin C, metformin, azithromycin and doxycycline on improving patients with COVID-19

Public title

Study the effectiveness of concomitant use of vitamin C, metformin, azithromycin and doxycycline on improving patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with coronavirus have mild to moderate viral infections diagnosed by an infectious disease specialist

Exclusion criteria:

Patients with severe lung involvement and severe respiratory symptoms patients with G6PD deficiency

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description

Using the random number table, patients are divided into two groups of 20. Each patient is assigned a 4-digit code based on the random number table, Based on the right number of patients code, the patients are divided into two groups. Patients whose last digit is 0, 2, 4, 6, 8 will be assigned to the intervention group and patients whose last digit is 1,3,5, 7, 9 will be assigned to the control group.

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

Ethics committee of Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-04-11, 1399/01/23

Ethics committee reference number

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

Disease recovery

Timepoint

The beginning of the study and the end of the study

Method of measurement

Based on laboratory and imaging criteria

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group will receive 250 mg of azithromycin daily for up to five days, 100 mg of doxycycline twice daily, 1.5 g of vitamin C every 6 hours, and 500 mg of metformin daily for one week.

Category

Treatment - Drugs

2

Description

The control group will receive the usual medication.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Dr. Faizullah Mansouri

Street address

Golestan Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code
6715847141
Phone
+98 83 3427 6306
Email
F_mansoury@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
Building No.2, Shahid Beheshti, Vice Chancellor for
Research Affairs, Kermanshah University of Medical
Sciences
City
kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3836 0014
Email
fnajafi@kums.ac.ir
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
Dr. Kamran Mansouri
Position
Faculty member of Kermanshah University of Medical
Sciences
Latest degree
Ph.D.
Other areas of specialty/work

Molecular medicine
Street address
Medical Biology Research Center, Parastar Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6714415185
Phone
+98 83 3427 6473
Email
kamranmansouri@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Faizullah Mansouri
Position
Faculty member of Kermanshah University of Medical
Sciences
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
Street address
Emam Hospital, Parastar Boulevard
City
Kermanshah
Province
Kermanshah
Postal code
6715847141
Phone
+98 83 3427 6306
Email
F_mansoury@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Kamran Mansouri
Position
Faculty member of Kermanshah University of Medical
Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Molecular medicine
Street address
Medical Biology Research Center, Parastar Boulevard
City
Kermanshah
Province
Kermanshah

Postal code

6714415185

Phone

+98 83 3427 6473

Email

kamranmansouri@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

3 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

Send E-mail to the responsible for the update to get the documentation

What processes are involved for a request to access data/document

Documentation will be emailed within a 15-day timeframe

Comments