

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 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.

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Molecular medicine

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#### Province

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**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**