

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigation of Anti-TNF- $\alpha$ (Infliximab) drug effectiveness in COVID-19 patients

#### Protocol summary

##### Study aim

Investigation of Anti-TNF- $\alpha$  (Infliximab) drug effectiveness in COVID-19 patients

##### Design

The study is a clinical trial, in parallel and double-blind, which will be performed on 40 people by block stratified randomization.

##### Settings and conduct

This is a double-blind study in which participants, health professionals, researchers, evaluators do not know whether the patient is receiving medication or a placebo.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include confirmation of the patient's test to Covid by RT-PCR or CT scan. Also, people who have oxygen levels below 88% and have high levels of inflammatory factors. Also excluded from the study were people with neurodegenerative diseases or conditions such as heart failure, high blood pressure, and active infections other than COVID 19.

##### Intervention groups

There are 2 intervention groups, including the group receiving the infliximab drug and the group receiving the placebo. Both groups of patients with Covid-19 have severe to critical clinical conditions

##### Main outcome variables

Changes in blood oxygen levels, ferritin, di-dimer, C-reactive protein as well as changes in white blood cell percentage

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201229049873N1**

Registration date: **2021-05-23, 1400/03/02**

Registration timing: **retrospective**

Last update: **2021-05-23, 1400/03/02**

Update count: **0**

##### Registration date

2021-05-23, 1400/03/02

##### Registrant information

###### Name

Jafar Majidi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 38 3333 0759

###### Email address

st-majidi.j@skums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-01-22, 1399/11/03

##### Expected recruitment end date

2021-03-13, 1399/12/23

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigation of Anti-TNF- $\alpha$  (Infliximab) drug effectiveness in COVID-19 patients

##### Public title

Infliximab effectiveness in COVID-19 patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Patients with Covid-19 with acute respiratory symptoms

between the ages of 18 and 60 who test positive for the SARS-CoV-19 virus by RT-PCR or by CT scan. Lung scan (subpleural lung involvement, bilateral circumference, and more than one area). Saturated oxygen is below 88% Respiratory rate more than 24 times per minute high CRP and D-dimer level, also ferritin above 1000 Lymphopenia with a count of less than 1100

**Exclusion criteria:**

Patients who have a positive test for PPD, HCV, HBS Patients Have a history of neurodegenerative diseases such as multiple sclerosis Patients with heart failure, hypertension, and infections other than Covid 19 infection.

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization was performed by block stratified randomization method in which the class of material and block size of four people were considered. Male and female patients were divided into quadruple blocks, respectively. In each block, two patients were randomly assigned to the intervention group and two patients to the control group. Randomization was performed for men and women separately so those female patients and male patients were placed in blocks separately. The randomization list was extracted by the software.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study, the drugs are coded A and B. None of the participants, health personnel, researchers, evaluators, and analysts know which drug code and which placebo code.

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahre-Kord University of Medical Sciences

**Street address**

Kashani ave

**City**

Shahre-Kord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

۸۸۱۵۷۱۳۴۷۱

**Approval date**

2020-12-23, 1399/10/03

**Ethics committee reference number**

IR.SKUMS.REC.1399.227

**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**

Changes in paraclinical outcomes

**Timepoint**

At the beginning of the study (before the intervention) and 7 and 14 days after the start of treatment

**Method of measurement**

Clinical and laboratory testing

**2**

**Description**

Blood oxygen levels

**Timepoint**

At the beginning of the study (before the intervention) and 7 and 14 days after the start of treatment

**Method of measurement**

Pulse oximeter

**3**

**Description**

Duration of hospitalization

**Timepoint**

From the beginning of the study.

**Method of measurement**

Clinical and vital signs

## Secondary outcomes

empty

## Intervention groups

1

### Description

"Intervention group:" Patients with Covid 19 who, in addition to the usual treatment regimens, receive a single dose of infliximab (4 mgr/kg) for 2 hours by infusion. The patient will be evaluated for vital signs, oxygen levels, and laboratory parameters at baseline and on the seventh and fourteenth days..

### Category

Treatment - Other

2

### Description

"Control group: "Patients with Covid 19 receiving common treatment regimens also receive a placebo. The patient will be evaluated for vital signs, oxygen levels, and laboratory parameters at baseline and on the seventh and fourteenth days.

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Hajar hospital

#### Full name of responsible person

Ahmad Raeisi

#### Street address

Hajar hospital,Parastar ave

#### City

Shahre-Kord

#### Province

Chahar-Mahal-va-Bakhtiari

#### Postal code

۸۸۱۶۷۵۴۶۳۳

#### Phone

+98 38 3222 1943

#### Email

Hajar-Hospital@skums.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Shahre-kord University of Medical Sciences

#### Full name of responsible person

Mehreban Sadeghi

#### Street address

Kashani ave

### City

Shahre-Kord

### Province

Chahar-Mahal-va-Bakhtiari

### Postal code

8815713471

### Phone

+98 38 3334 2414

### Email

sadeghi@skums.ac.ir

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

#### Full name of responsible person

Akbar Soleymani

#### Position

Associate professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Pulmonary Diseases

#### Street address

Kashani hospital,Parastar ave

#### City

Shahre-Kord

#### Province

Chahar-Mahal-va-Bakhtiari

#### Postal code

۸۸۱۶۷۵۸۹۱۵

#### Phone

+98 38 3226 4825

#### Email

dr.akbarsoleymani@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shahre-kord University of Medical Sciences

#### Full name of responsible person

Mohammad Moosavi

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Rheumatology

**Street address**

Hajar hospital, Parastar ave

**City**

Shahre-Kord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8816854633

**Phone**

+98 38 3222 1943

**Email**

moosavi@skums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Jafar Majidi

**Position**

Student

**Latest degree**

Master

**Other areas of specialty/work**

Immunology

**Street address**

Department of immunology, School of Medicine,  
Shahre-Kord university of medical science,  
Rahmatiyeh

**City**

Shahre-Kord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8813833435

**Phone**

+98 38 3333 5653

**Email**

st-majidi.j@skums.ac.ir

**Sharing plan**

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

Yes - There is 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**

Yes - There is 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

**Title and more details about the data/document**

All potential data can be shared after blinding

**When the data will become available and for how long**

Six months after publishing

**To whom data/document is available**

Researchers working in academic institutions

**Under which criteria data/document could be used**

For research purposes and meta-analysis studies

**From where data/document is obtainable**

Jafar Majidi, Department of immunology, School of  
Medicine, Shahre-Kord University of Medical Sciences,  
Rahmatieh

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

Official letter to the researchers

**Comments**