Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of Anti-TNF-α (Infliximab) drug effectiveness in COVID-19 patients

Protocol summary

Study aim
Investigation of Anti-TNF-α (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
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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-α (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
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Phone
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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
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Kashani ave
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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
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Person responsible for scientific inquiries

Contact
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Shahre-kord University of Medical Sciences
Full name of responsible person

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Position
Assistant Professor

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Subspecialist

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Student

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Other areas of specialty/work
Immunology

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

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Email
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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 mounts 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