Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the effectiveness of ACTEMRA (TOCILIZUMAB) and REMICADE (INFLIXIMAB) in patients with Covid19

Protocol summary

Study aim
Determining and comparing the effectiveness of Tocilizumab and Infliximab in patients with Covid19

Design
The clinical trial has two parallel groups, one blind, non-random, phase 2-3 on 40 patientsمداخله

Settings and conduct
The intervention is performed for Covid19 patients with severe hospitalization in Shahrekord hospitals. One of the two drugs, tocilizumab and infliximab, are injected into patients at 8 mg and 5 mg per kg body weight, respectively, according to the treating physician. Patients are aware of receiving one of these two drugs but do not know which of the two

Participants/Inclusion and exclusion criteria
1. People aged 25-70 years with Covid19 (based on RT-PCR test for SARS-CoV-19 virus or CT scan criteria) 2. The presence of symptoms indicates the severity of the disease 3. ppd test, and markers of viral hepatitis are negative 4. No pregnancy

Intervention groups
Two groups of patients with severe covid19 disease who received conventional therapies received treatment with tocilizumab and infliximab (one drug in each group).

Main outcome variables
Ferritin; D-dimer; Lactate dehydrogenase; Complete blood cell count; Blood oxygen saturation; Reactive protein c

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220208053970N1**
Registration date: **2022-03-12, 1400/12/21**
Registration timing: **registered_while_recruiting**
Last update: **2022-03-12, 1400/12/21**
Update count: **0**

Registration date
2022-03-12, 1400/12/21

Registrant information
Name
Amir hossein koohi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 3230 5627
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st-kouhi.a@skums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-03-12, 1400/12/21

Expected recruitment end date
2022-08-11, 1401/05/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of ACTEMRA (TOCILIZUMAB) and REMICADE (INFLIXIMAB) in patients with Covid19

Public title
Effect of Toscilizumab and Infliximab on Covid 19

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:

People with Covid 19 (based on RT-PCR test for SARS-CoV-19 virus or CT scan criteria) People between the ages of 25 and 70 Symptoms indicate severe disease (more than 50% of lung involvement in CT or oxygen saturation below 90% or respiratory rate greater than 30 per minute) Elevated CRP, ferritin and other inflammatory markers

Exclusion criteria:

People who test positive for PPD, HCV, HBV and have infections other than Covid 19 infection Pregnancy and pregnancy intention Mild involvement or in the early stages of Covid 19

Age

From **25 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, patients with Covid19 are divided into two groups and according to the treating physician, one of the drugs Tocilizumab and Infliximab is injected according to the inclusion criteria. In this study, patients are aware and satisfied to receive one of these two drugs, but they are blind to which of these drugs, but the doctor and other research team are aware of which drug to receive by which group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahrekord University of Medical Sciences (Research Ethics Committee)

Street address

Hajar Hospital, Parastar Ave

City

shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816754633

Approval date

2022-01-25, 1400/11/05

Ethics committee reference number

IR.SKUMS.REC.1400.220

Health conditions studied

1

Description of health condition studied

covid19

ICD-10 code

U10

ICD-10 code description

covid19

Primary outcomes

1

Description

ferritin

Timepoint

Before the intervention and five days after receiving the drug

Method of measurement

Elisa

2

Description

d-dimer

Timepoint

Before the intervention and five days after receiving the drug

Method of measurement

Bio-Lis

3

Description

C-Reactive Protein

Timepoint

Before the intervention and five days after receiving the drug

Method of measurement

Bio-Lis

4

Description

Lactate Dehydrogenase

Timepoint

Before the intervention and five days after receiving the drug

Method of measurement

Bio-Lis

5

Description
complete blood count
Timepoint
Before the intervention and five days after receiving the drug
Method of measurement
sysmex

6

Description
Erythrocyte Sedimentation Rate
Timepoint
Before the intervention and five days after receiving the drug
Method of measurement
Sediman Reader

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: This group of patients with Covid19 who have received standard treatments ,receive tocilizumab brand name ACTEMRA and TEMZIVA from ROCHE PHARMA and ARIOGEN PHARMED factories at a dose of 8 mg / kg in one or two doses two days apart.
Category
Treatment - Drugs

2

Description
Intervention group 2: This group of patients with Covid19 who have received standard treatments, receive an infliximab brand name REMICADE from JANSSEN factory at a dose of 5 mg/kg
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar hospital
Full name of responsible person
Amirhossein Koohi Esfahani
Street address
Parastar Ave
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2

Recruitment center
Name of recruitment center
Kashani hospital
Full name of responsible person
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Kashani@skums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Esfandiar Heydarian
Street address
Building No. 2, University Headquarters.Kashani Blvd
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Shahrekord
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Chahar-Mahal-va-Bakhtiari
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۸۸۱۵۷۱۳۴۷۱
Phone
+98 38 3334 2414
Email
vcrt@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
Amir hossein Koohi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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121Unit, Ghaem complex, Pars St, Shariati St
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
Name of organization / entity
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Position
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Medical doctor
Other areas of specialty/work
Internal Medicine
Street address
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st-kouhi.a@skums.ac.ir

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
Undecided - It is not yet known if there will be a plan to make this available
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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data from the study can be shared after being unidentified
When the data will become available and for how long
Access begins in the winter of 1401
To whom data/document is available
The data will be available to researchers and academics
Under which criteria data/document could be used
Access will be possible to assist with future studies and scientific reviews
From where data/document is obtainable
Contact Dr. Amir Hossein Koohi to receive data amirh1391@gmail.com
What processes are involved for a request to access data/document
After introducing the applicant and stating the purpose of the information request, as well as the commitment not to use it anymore, it can be received via email.

Comments