

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Evaluating the efficacy and safety of Adalimumab in patients with COVID-19

Protocol summary

Study aim

Evaluating the efficacy and safety of Adalimumab (CinnaGen Co.) in patients with COVID-19

Design

This is a phase 2, interventional, unicenter, open label and two-arm clinical trial that is performed on two groups of 20 people.

Settings and conduct

This is an interventional, unicenter clinical trial in Shariati hospital on patients with severe COVID-19 who are over 18 years of age and hospitalized.

Participants/Inclusion and exclusion criteria

Patients with a definitive diagnosis of COVID-19 based on PCR who are at least 18 years old, have signed the consent form and the TNF alpha levels in their blood samples are as 3 times as much as normal range or have a remarkable increase in CRP or Ferritin are enrolled. Also the participants are not enrolled in other clinical trials at the same time; are not pregnant or breastfeeding; are not allergic to the drug or the ingredients in the formulation; do not have other active infections, heart failure or active rheumatic diseases and do not take immunosuppressive drugs.

Intervention groups

In addition to conventional treatment, the interventional group receive 80mg of adalimumab subcutaneously as a single dose. The Control group receive conventional drug treatment.

Main outcome variables

Mortality rate in Day 28

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150303021315N22**

Registration date: **2021-01-27, 1399/11/08**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-27, 1399/11/08**

Update count: **0**

Registration date

2021-01-27, 1399/11/08

Registrant information

Name

Nassim Anjidani

Name of organization / entity

Orchid Pharmed

Country

Iran (Islamic Republic of)

Phone

+98 21 4347 3000

Email address

amini@orchidpharmed.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-04, 1399/04/14

Expected recruitment end date

2021-01-30, 1399/11/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the efficacy and safety of Adalimumab in patients with COVID-19

Public title

Adalimumab effectiveness in COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with the ability to comprehend and willingness to participate in the trial. Patients who are at least 18 years old at the beginning of trial. Patients with Fever higher than 37.8 C, Cough, shortness of breath accompanied by SpO₂ ≤93, who have a confirmed diagnosis of SARS-CoV-2 infection using RT-PCR. patients with increased level of TNF-alpha to 3 times as much as normal range or with remarkable increase in CRP or Ferritin.

Exclusion criteria:

Patients attending other clinical trials at the same time. patients who are pregnant or breastfeeding. patients with (ALT/AST> 5ULN, ANC <0.5 (x10⁹/L), Platelet count<50 (x10⁹/L) based on laboratory findings. People with active immune-related rheumatic diseases who have been treated with anti-TNF medications for the last 6 months. People taking immunosuppressive drugs. People who are allergic to adalimumab or other components of the formulation of these drugs. People with active pulmonary tuberculosis or other active bacterial or fungal infections (Based on IGRA, procalcitonin and blood culture) People with heart failure (grades 3 and 4 of NYHA). History of demyelinating diseases in the patient or his/her family

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be assigned to treatment groups using a stratified randomization by R-CRAN software version 4.0.3. Blocks (with the size 2 or 4) will be made using permuted block randomization for a total of 40 patients with 1:1 allocation ratio. stratification is performed by sex (2 levels) and age (18-40 and 40-60). The randomization number will be assigned in a consecutive way.

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

Research Ethics Committee of Tehran University of Medical Sciences

Street address

Sixth floor, Research Deputy of Tehran University of Medical Sciences, Ghods Street, Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2020-04-05, 1399/01/17

Ethics committee reference number

IR.TUMS.VCR.REC.1399.136

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Mortality rate in day 28

Timepoint

From day 1 to day 28

Method of measurement

During the hospital stay based on the doctor's approval and then by phone call and taking a history in day 28

Secondary outcomes

1

Description

Changes in laboratory data

Timepoint

Day 1, day 3-5 and at the time of discharge

Method of measurement

Laboratory test

2

Description

2. Changes in SpO₂

Timepoint

Day 1, day 3-5 and at the time of discharge

Method of measurement

Physical examination

3

Description

Radiographic changes of the lungs

Timepoint

Day 1 and week 6

Method of measurement

CT-scan

4

Description

Duration (days) of supplemental oxygenation.

Timepoint

Day 1 to the time of discharge

Method of measurement

Clinical evaluation

5

Description

Percent of patients with improvement in oxygenation (at least one step decrease in oxygenation supply)

Timepoint

Day 1 to the time of discharge

Method of measurement

Clinical evaluation

6

Description

Incidence of any adverse events (AEs) during the study.

Timepoint

Day 1 to the time of discharge

Method of measurement

Clinical evaluation

7

Description

Changes in findings related to physical examinations and vital signs

Timepoint

Day 1 to day 3-5 and at the time of discharge

Method of measurement

Clinical evaluation

Intervention groups

1

Description

Intervention group: The intervention group, in addition to standard treatment, receives 80 mg of adalimumab (with the concentration of 40mg/0.8ml) produced by Cinnagen Company (CinnoRA®) subcutaneously and as a single dose. Standard treatment: Oxygen therapy, using a mask or nasal cannula based on the patients' O₂ saturation. Corticosteroids (if more than 5 days since the onset of symptoms have passed or SatO₂ without adjuvant oxygen is below 90) are prescribed for a maximum of 2 weeks as following: Dexamethasone 6-8 mg/day or Prednisolone 0.5 mg/kg/day (max: 40mg).

Anticoagulants, including heparin or enoxaparin:

Subcutaneous enoxaparin in patients with GFR above 30: For BMI below 30=40mg/day subcutaneously, For BMI above 30=60mg/day subcutaneously or Heparin 5000U, TDS subcutaneously. Due to the lack of conclusive evidence for effectiveness of antiviral therapies in hospitalized patients with COVID-19, one of these antivirals including Lopinavir/Ritonavir, Atazanavir or Remdesivir may be prescribed based on physician's decision.

Category

Treatment - Drugs

2

Description

Control group: The control group receives standard treatment including the following: Oxygen therapy, using a mask or nasal cannula based on the patients' O₂ saturation. Corticosteroids (if more than 5 days since the onset of symptoms have passed or SatO₂ without adjuvant oxygen is below 90) are prescribed for a maximum of 2 weeks as following: Dexamethasone 6-8 mg/day or Prednisolone 0.5 mg/kg/day (max: 40mg). Anticoagulants, including heparin or enoxaparin: Subcutaneous enoxaparin in patients with GFR above 30: For BMI below 30= 40mg/day subcutaneously, For BMI above 30= 60mg/day subcutaneously or Heparin 5000U, TDS subcutaneously. Due to the lack of conclusive evidence for effectiveness of antiviral therapies in hospitalized patients with COVID-19, one of these antivirals including Lopinavir/Ritonavir, Atazanavir or Remdesivir may be prescribed based on physician's decision.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Mona Talschian

Street address

Shariati hospital, Jalal al-e-Ahmad Hwy, North Kargar Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ahmadreza Jamshidi

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jamshida@tums.ac.ir

Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Mona Talschian

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Shariati Hospital, Jalal Al-Ahmad Hwy, North Kargar St.

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Person responsible for scientific inquiries

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Tehran University of Medical Sciences

Full name of responsible person

Ahmadreza Jamshidi

Position

Professor

Latest degree

Subspecialist

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Others

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Person responsible for updating data

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Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

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

Undecided - It is not yet known if there will be a plan to make this available