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 Boulvard

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

C0VID-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 standarad 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
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Fax
+98 21 8863 3039
Email
shariatihosp@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ahmadreza Jamshidi
Street address
Tehran university of medical science,
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 6640 5357
Fax
+98 21 8895 3003
Email
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
Street address
Shariati Hospital, Jalal Al-Ahmad Hwy, North Kargar St.
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Fax
+98 21 8863 3039
Email
shariatihosp@tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ahmadreza Jamshidi
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Others
Street address
Tehran university of medical science,
City
Tehran
Province
Tehran
Postal code
1417613151
Phone
+98 21 6640 5357
Fax
+98 21 8895 3003
Email
jamshida@tums.ac.ir

Person responsible for updating data

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
Street address
Shariati Hospital, Jalal Al-Ahmad Hwy, North Kargar St.
City
Tehran
Province
Tehran
Postal code
1411713135
Phone

+98 21 8490 1000
Fax
+98 21 8863 3039
Email
shariatihosp@tums.ac.ir

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