

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of subcutaneous adalimumab on the prognosis of patients with COVID-19: a pilot study in patients admitted to Afzalipour hospital in Kerman

Protocol summary

Study aim

Evaluation of the effect of subcutaneous adalimumab on the prognosis of patients with COVID-19

Design

Clinical trial with parallel control group with parallel, non-blind, non-randomized phase 2 on 20 patients.

Settings and conduct

In Afzalipour Hospital, on the first day of hospitalization of this study, which will be performed non-blindly, patients of the intervention group will receive 40 mg subcutaneous adalimumab made by Sinagen factory. In the intervention group, as in the control group, adjuvant therapies such as vitamins C and D along with remdesivir and heparin will be prescribed according to the treatment protocol.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients suffering severe COVID-19; patient consent; age 60_70 years old. Exclusion criteria: Fever (body temp above 40°C); any active bacterial or fungal infection; positive blood and urine culture; history of chronic obstructive pulmonary disease; history of tuberculosis, heart failure, infectious skin wounds; history of multiple sclerosis; very severe/critical stage of the disease (shock, encephalopathy, myocardial lesion, coagulation, and renal impairment); abnormal liver tests in the form of liver enzymes more than 2 times normal; glomerular filtration rate (GFR) less than or equal to 30.

Intervention groups

Patients of the intervention group will receive 40 mg subcutaneous adalimumab made by Sinagen factory. In the intervention group, as in the control group, adjuvant therapies such as vitamins C and D along with remdesivir and heparin will be prescribed according to the treatment protocol.

Main outcome variables

C-reactive protein (CRP); Lactate Dehydrogenase (LDH); SpO2 level; Respiratory rate per minute; Hospitalization

stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220112053701N1**

Registration date: **2022-02-26, 1400/12/07**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-26, 1400/12/07**

Update count: **0**

Registration date

2022-02-26, 1400/12/07

Registrant information

Name

Amirhossein Arabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3428 9950

Email address

aha6765@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-19, 1400/11/30

Expected recruitment end date

2022-04-18, 1401/01/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of subcutaneous adalimumab on the prognosis of patients with COVID-19: a pilot study in patients admitted to Afzalipour hospital in Kerman

Public title

Evaluation of the effect of subcutaneous adalimumab on the prognosis of patients with COVID-19: a pilot study

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Severe COVID-19 (respiratory rate more than 30 per minute or oxygen saturation less than 90% or more than 50% lung parenchyma involvement on the patient's CT scan) Patient's consent Age: 60_70 years old

Exclusion criteria:

Fever (body temp above 40°C) Any active bacterial or fungal infection Positive blood and urine culture History of chronic obstructive pulmonary disease History of tuberculosis Heart failure Infectious skin wounds History of multiple sclerosis Very severe/critical stage of the disease (shock, encephalopathy, myocardial lesion, coagulation, and renal impairment) abnormal liver tests in the form of liver enzymes more than 2 times normal GFR less than or equal to 30

Age

From **60 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Not randomized

Randomization description**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**

Ethics committee of Kerman University of Medical

Sciences

Street address

Haft-Bagh Highway

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2022-02-11, 1400/11/22

Ethics committee reference number

IR.KMU.REC.1399.655

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**

C-reactive protein (CRP)

Timepoint

First and 5th day

Method of measurement

using latex agglutination tests and a bionic CRP quantitative detection kit

2**Description**

Lactate Dehydrogenase (LDH)

Timepoint

First and 5th day

Method of measurement

routine commercial kits (Pars Azmoon Co.,Iran).

3**Description**

SpO2 level

Timepoint

First and 5th day

Method of measurement

by pulse oximeter

4**Description**

Respiratory rate per minute

Timepoint

First and 5th day

Method of measurement

Counting the number of breaths for one minute by counting how many times the chest rises

<https://ah.kmu.ac.ir/en>

Sponsors / Funding sources

5

Description

Hospitalization stay

Timepoint

discharge time

Method of measurement

Counting the number of days hospitalized

Secondary outcomes

empty

Intervention groups

1

Description

On the first day of hospitalization of this study, which will be performed non-blindly, patients of the intervention group will receive 40 mg subcutaneous adalimumab made by Sinagen factory. In the intervention group, as in the control group, adjuvant therapies such as vitamins C and D along with remdesivir and heparin will be prescribed according to the treatment protocol.

Category

Treatment - Drugs

2

Description

Control group: adjuvant therapies such as vitamins C and D along with remdesivir and heparin will be prescribed according to the treatment protocol.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour hospital

Full name of responsible person

Mehrdad Farrokhnia

Street address

Afzalipour hospital, Emam khomeini Blvd.

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Email

ah@kmu.ac.ir

Web page address

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Reza MalekpourAfshar

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7616913555

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Email

malekpour@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Mehrdad farrokhnia

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Mehrdad farrokhnia

Position

Associate professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Amir Hossein Arabi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Infectious diseases

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Web page address

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

Not applicable

Data Dictionary

Not applicable