

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Evaluation of adalimumab effect on clinical symptoms including respiratory distress, oxygen saturation and lung involvement of patients with COVID-19

Protocol summary

Study aim

The purpose of this study is to determine the effect of Adalimumab on clinical symptoms of patients with COVID-19

Design

Phase II, single-blinded, randomized, parallel-group clinical trial on 100 patients

Settings and conduct

This study will be performed at Baqiyatallah hospital in Tehran. 50 patients receiving routine antiviral drug and chloroquine will receive 40 mg subcutaneous abdominal injection of Adalimumab. 50 control group patients receive only routine antiviral drug and chloroquine. Since this is a single-blind study, only patients participating in this study are blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: suffering from COVID-19, Respiratory distress with over 30 breaths per minute, O₂ saturation less than 93% at rest, PaO₂/Fio₂ less than 300 mmHg, HRCT indicating COVID-19, positive PCR test result. Non-inclusion criteria: -

Intervention groups

Control group: Receiving standard antiviral treatment and Chloroquine. Intervention group: Receiving drugs used in control group plus subcutaneous injection of 40 mg adalimumab into the periumbilical region

Main outcome variables

Disease severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171105037262N4**

Registration date: **2020-06-18, 1399/03/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-18, 1399/03/29**

Update count: **0**

Registration date

2020-06-18, 1399/03/29

Registrant information

Name

mohammadhossein pourhanifeh

Name of organization / entity

kashan university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 31 5558 0988

Email address

pourhanifeh-mh@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-29, 1399/02/10

Expected recruitment end date

2020-07-31, 1399/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of adalimumab effect on clinical symptoms including respiratory distress, oxygen saturation and lung involvement of patients with COVID-19

Public title

Adalimumab effect on COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Having COVID-19 Respiratory distress with over 30 breaths per minute O2 saturation less than 93% at rest PaO₂/Fio₂ less than 300 mmHg HRCT indicating COVID-19 positive PCR test result

Exclusion criteria:

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
After specifying the sample size, blocks of size 4 consisting of A and B letters are formed (6 blocks). Then, each of the blocks is numbered 1 to 6 and based on the selected numbers from random numbers table, we form a sequence of blocks, in which the letters A and B are located, and then randomly one of the letters are considered as the drug group and the other letter as the control group. This method is referred to as "Permuted Blocked Randomization".

Blinding (investigator's opinion)
Single blinded

Blinding description
Since this is a single-blind study, our blindness would be single-blinded and only patients participating in this study are blind

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah University of Medical Science

Street address

Mollasadra

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2020-04-05, 1399/01/17

Ethics committee reference number

IR.BMSU.REC.1399.062

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

Disease severity

Timepoint

At the beginning and end of the intervention

Method of measurement

According to protocol and clinical symptoms

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 50 patients with COVID-19 who receive routine antiviral treatment and chloroquine, have more than normal levels of TNF- α , and are at risk of critical disease statement (1-respiratory failure that needs mechanical ventilation, 2-shock, 3-any organ failure, 4-need to be admitted in ICU) will receive subcutaneous injection of anti-TNF- α (adalimumab), 40 mg, in periumbilical region of the abdomen. According to altered clinical and laboratory findings, mentioned dose can be repeated

Category

Treatment - Drugs

2

Description

Control group: 50 matched patients receiving equal antiviral treatment and chloroquine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baghiyatallah hospital

Full name of responsible person

Hassan Nikoueinejad

Street address

Mollasadra street

City

Tehran

Province

Tehran

Postal code

1435915371

Phone

+98 21 8805 1511

Email

hnikuinejad@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Gholamhossein Alishiri

Street address

Mollasadra

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 5250

Email

R.bmsu@yahoo.com

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

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hassan Nikoueinejad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Immunology

Street address

Mollasadra

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 5250

Email

hnikuinejad@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Hassan Nikoueinejad

Position

Assosiate Professor

Latest degree

Specialist

Other areas of specialty/work

Immunology

Street address

Mollasadra

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 5250

Email

hnikuinejad@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Hossein Pourhanifeh

Position

student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

Street address

Ghotb-e-Ravandi Blvd

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5558 0988

Email

mhph.lord.1996@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available