

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Evaluating the efficacy and safety of Adalimumab in patients with acute respiratory distress syndrome caused by COVID-19

Protocol summary

Study aim

Evaluating the efficacy and safety of Adalimumab as a treatment option for patients with COVID-19

Design

Prospective clinical trial with parallel randomized control and treatment, open-label groups, phase 2 trial on 60 patients. Block randomization was done using online website (www.sealedenvelope.com/simple-randomiser/v1/lists).

Settings and conduct

Place of study: Masih Daneshvari Hospital. How to do the study: 60 patients with COVID-19, using block randomization will be divided in to intervention and control group. This is an open-label study.

Participants/Inclusion and exclusion criteria

Patients between 18 and 65 years old who have laboratory confirmed COVID-19 (Corona Virus Disease-19) with RT-PCR (Real-Time Polymerase Chain Reaction) or CT scan and are sever or critically ill, are included in the study. Furthermore, patients must have CRP rise two times the normal value and IL-6 above 7 pg/ml. Study exclusion criteria is as follows: acute or chronic renal failure (creatinine rise above 3 mg/dL during the last 48 hours or GFR les than 30 mL/min), liver failure (LFT rise five times the upper limit or three time rise in symptomatic patients or Child Pugh C or D), allergic reaction while injecting adalimumab with severe extravasation or anaphylactic reaction, patient with mild disease.

Intervention groups

Patients in treatment group received single dose of adalimumab ampule (CinnoRA, CinnaGen), 40 mg subcutaneously with supportive treatments according to national guideline. Furthermore, patients in control group received supportive care according national guideline.

Main outcome variables

Hospital discharge, need for oxygen support, need for mechanical ventilation, and 28 days mortality.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151227025726N23**

Registration date: **2020-11-10, 1399/08/20**

Registration timing: **retrospective**

Last update: **2020-11-10, 1399/08/20**

Update count: **0**

Registration date

2020-11-10, 1399/08/20

Registrant information

Name

Farzaneh Dastan

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 912 270 5933

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-06, 1399/05/16

Expected recruitment end date

2020-11-06, 1399/08/16

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 acute respiratory distress syndrome caused by COVID-19

Public title

Evaluating the effects of Adalimumab in patients with acute respiratory distress syndrome caused by COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between 18 and 65 years old. Laboratory confirmed COVID-19 (Corona Virus Disease-19) with RT-PCR (Real-Time Polymerase Chain Reaction) or CT scan. Sever or critically ill patients. CRP rise two times the normal value. IL-6 above 7 pg/ml. Signed the consent form

Exclusion criteria:

Acute or chronic renal failure (creatinine rise above 3 mg/dL during the last 48 hours or GFR less than 30 mL/min) Liver failure (LFT rise five times the upper limit or three time rise in symptomatic patients or Child Pugh C or D) Allergic reaction while injecting adalimumab with severe extravasation or anaphylactic reaction. Patient with mild disease Pregnancy or breastfeeding Patients with IL-6 below 7 pg/ml Patient with latent or active TB or any other active infection History of active peptic ulcer Receiving drugs effective on interleukin or TNF alpha History of malignancy Patient with heart failure

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method was used in this study. Ten blocks including six patients generated with online website (www.sealedenvelope.com/simple-randomiser/v1/lists). In each block, three patients will be assigned to adalimumab group and three patients will be assigned to control group.

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 Shahid Beheshti University of Medical Sciences

Street address

3 rd floor, School of Medicine, Evin St, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2020-08-05, 1399/05/15

Ethics committee reference number

IR.SBMU.NRITLD.REC.1399.154

Health conditions studied

1

Description of health condition studied

COVID-19 pneumonia

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Clinical improvement (hospital discharge)

Timepoint

Daily until discharge

Method of measurement

Medical record

2

Description

Clinical improvement (length of time in which patient needs oxygen therapy)

Timepoint

Daily until discharge

Method of measurement

Medical record

3

Description

Need for mechanical ventilation

Timepoint

Daily until discharge

Method of measurement

Medical record

4

Description

28 days mortality

Timepoint

From the first day of admission until 28 days

Method of measurement

Medical record

Secondary outcomes

1

Description

Number of days admitted to critical care unit

Timepoint

Daily until discharge

Method of measurement

Medical record

2

Description

Length of hospital stay

Timepoint

Daily until discharge

Method of measurement

Medical record

3

Description

Lung radiological changes

Timepoint

First day of the study then at day 5

Method of measurement

Computed tomography

4

Description

RT-PCR result

Timepoint

First day of the study then at day 5

Method of measurement

Medical record

Intervention groups

1

Description

Intervention group: Patients in treatment group received single dose of adalimumab ampule (CinnoRA, CinnaGen), 40 mg subcutaneously with supportive treatments according to national guideline. Supportive treatment includes interferon b1a (Resigen) 44 microgram every other day for 3 doses + Lopinavir/Ritonavir 200-50 mg (Hetero Labs Limited) 2 Tab twice daily for 7 days.

Category

Treatment - Drugs

2

Description

Control group: Patients in control group received supportive care according national guideline. Supportive treatment includes interferon b1a (Resigen) 44 microgram every other day for 3 doses + Lopinavir/Ritonavir 200-50 mg (Hetero Labs Limited) 2 Tab twice daily for 7 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Farzaneh Dastan

Street address

Masih Daneshvari Hospital, Shahid Bahonar Street (Niyavaran), Darabad.

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f_dastan@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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3rd floor, School of Medicine, Evin St, Shahid Chamran Highway

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Atefeh Fakharian

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Farzaneh Dastan

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

Zahra Mirshafiei Langari

Position

Hospital pharmacist

Latest degree

Medical doctor

Other areas of specialty/work

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

Yes - There is 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

Title and more details about the data/document

All potential data can be shared after blinding

When the data will become available and for how long

Six months after publishing the results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

For research purposes and meta-analysis studies

From where data/document is obtainable

Dr. farzaneh Dastan, Dr. Masih Daneshvari Hospital,
Daar-Abad, Niavaran

What processes are involved for a request to access data/document

Official letter to the researchers through Email
(fzh.dastan@gmail.com).

Comments