Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 adalimimab 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)

Phone
+98 912 270 5933

Email address
f_dastan@sbmu.ac.ir

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 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 adalimimab 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 pectic 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 Committe 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.
City
Tehran
Province
Tehran
Postal code
1956944413
Phone
+98 21 2712 3000
Email
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
Street address
3rd floor, School of Medicine, Evin St, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1983963113
Phone
+98 21 23871
Email
mpd@sbmu.ac.ir
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
Street address
Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran
City
Tehran
Province
Tehran
Postal code
19569-44413
Phone
+98 21 2712 2066
Email
Atefeh.fakharian7@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Farzaneh Dastan
Position
Assisstant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy, Shahid Beheshti University of Medical Sciences, Intersection of Niyayesh Highway, Valieasr St.
City
Tehran
Province
Tehran
Postal code
1991953381
Phone
+98 21 8820 0118
Email
f_dastan@sbmu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Zahra Mirshafiei Langari
Position
Hospital pharmacist
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
Street address
Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran
City
Tehran
Province
Tehran
Postal code
19569-44413
Phone
+98 21 2712 2066
Email
z.mirshafei@gmail.com

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