

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation of the efficacy and safety of Adalimumab and methylprednisolone pulse therapy in treatment of Covid-19 patients with ARDS

Protocol summary

Study aim

Evaluation of the efficacy and safety of Adalimumab and Methylprednisolone pulse therapy in treatment of Covid-19 patients with ARDS

Design

This study is a two arm parallel group, randomized clinical trial in phase 2 which will be carried out on 40 hospitalized COVID-19 patients. Patients randomly divided into two groups.

Settings and conduct

This clinical trial will be carried out on 40 hospitalized COVID-19 patients in Intensive care unit of imam Reza hospital of AJA university of medical sciences, Iran. Patients will be received 1000mg Methylprednisolone pulse for 3 days and single 40 mg dose of Adalimumab.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients admitted to ICU with moderate to severe Covid-19 infection needs respiratory support PaO₂/FiO₂ less than 300 Progression of disease severity and not responding to standard treatment Prediction of intubation need in next 24 hours and LDH more than 450 Exclusion Criteria: Uncontrolled diabetes mellitus Active bacterial, fungal infection Procalcitonin more than 0.5 History of hypersensitivity to corticosteroids Active GI bleeding

Intervention groups

Control group: receive standard regimen for COVID-19 Intervention group: receive standard regimen for COVID-19 plus Methylprednisolone (1000 mg for 3 days) and Adalimumab (single stat 40 mg dose).

Main outcome variables

Changes in respiratory distress Changes in O₂ Saturation Extubation Discharge from ICU Mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200406046963N2**
Registration date: **2021-07-31, 1400/05/09**
Registration timing: **registered_while_recruiting**

Last update: **2021-07-31, 1400/05/09**

Update count: **0**

Registration date

2021-07-31, 1400/05/09

Registrant information

Name

Reza Mosaed

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8609 6001

Email address

reza.mosaed@ajaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-18, 1400/03/28

Expected recruitment end date

2021-09-19, 1400/06/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and safety of Adalimumab and

methylprednisolone pulse therapy in treatment of Covid-19 patients with ARDS

Public title

Evaluation of the efficacy and safety of Adalimumab and methylprednisolone pulse therapy in treatment of Covid-19 patients with Acute respiratory distress syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with moderate to severe Covid-19 admitted to ICU PaO₂/FiO₂ Less than 300 LDH more than 450 Progression of disease severity and not responding to standard treatment prediction of intubation for next 24 hours

Exclusion criteria:

Uncontrolled diabetes mellitus Active GI bleeding history of corticosteroid hypersensitivity severe electrolyte imbalances Procalcitonin more than 0.5 active bacterial, viral (HIV, Hepatitis) and fungal infection

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with random allocation software and allocate patients to two groups of investigation (A) and control (B)

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 AJA University of Medical Sciences

Street address

Etemadzadeh Ave, west Fatemi street

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2021-05-19, 1400/02/29

Ethics committee reference number

IR.AJAUMS.REC.1400.032

Health conditions studied

1

Description of health condition studied

COVID-19 Disease

ICD-10 code

U07.2,

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Mortality rate

Timepoint

from including to study to 60 days

Method of measurement

observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients hospitalized with COVID-19 disease who in addition to their standard treatment (Hydroxychloroquine 400mg daily) will be received 1000mg/day Methylprednisolone for 3 days and a stat 40 mg dose of Adalimumab.

Category

Treatment - Drugs

2

Description

Control group: Patients hospitalized with COVID-19 disease who are received standard treatment (Hydroxychloroquine 400mg daily)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Ebrahim Hazrati

Street address

Etemadzadeh Ave, west Fatemi st

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 5072

Email

dr.hazart.e@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Ramin Hamidi Farahani

Street address

Etemadzadeh ave, west Fatemi st

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

Rgsramin@yahoo.com

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

Yes

Title of funding source

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Ebrahim Hazrati

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Etemadzadeh Ave, west Fatemi st

City

Tehran

Province

Tehran

Postal code

14117118541

Phone

+98 21 8609 6350

Email

dr.hazart.e@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Ebrahim hazrati

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Etemadzadeh Ave, west Fatemi st

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6350

Email

dr.hazart.e@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Reza Mosaed

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

Etemadzadeh Ave, west Fatemi st

City

Tehran

Province

Tehran

Postal code

1411718541

Phone

+98 21 8609 6001

Email

reza.mosaed@ajaums.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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

not shared

When the data will become available and for how long

After acceptance of a journal

To whom data/document is available

All medical professionals and scientists

Under which criteria data/document could be used

There is no restriction on access to information

From where data/document is obtainable

Dr.Ebrahim Hazrati, AJA University of Medical sciences

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

Refer to the project supervisor

Comments