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

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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 sever 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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Artesh University of Medical Sciences

Full name of responsible person
Ramin Hamidi Farahani

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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
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

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Person responsible for updating data

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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 scientiscts
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