Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Evaluation of the Efficacy and Safety of Colchicine plus Methylprednisolone Pulse Therapy in Treatment of Covid-19 Patients with ARDS

Protocol summary

Study aim
Evaluation of the efficacy and safety of colchicine plus methylprednisolone pulse therapy in treatment of Covid-19 patients with ARDS

Design
A clinical trial with control group, double blinded, randomized with random numbers table, phase2 with 80 patients.

Settings and conduct
A clinical trial on 80 patients with progressive covid19 disease admitted in Imam Reza Hospital ICU. Study is randomized and double blinded (both patients and assessor kept blind). in intervention group Methylprednisolone pulse therapy and Colchicine is used in addition to standard treatment in control group.

Participants/Inclusion and exclusion criteria
Covid-19 ICU-admitted patients with moderate to severe ARDS

Intervention groups
Control group: Receiving standard treatment for patients who have ARDS due to covid19 disease including Dexamethasone (8mg daily till 10 days), Interferon beta1(250 microgram till 7 days) and Remdesivir (initial dose: 200mg then 100mg daily) Intervention group: in addition to receiving standard treatment for patients who have ARDS due to covid19 disease, this group will receive Methylprednisolone pulse therapy (500mg each 12h until 3 days) and Colchicine pill (2mg stat then 1mg daily)

Main outcome variables
Evaluation of the efficacy of colchicine plus methylprednisolone pulse therapy in treatment of Covid-19 patients with Respiratory distress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201229049872N1**
Registration date: **2021-04-22, 1400/02/02**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-22, 1400/02/02**
Update count: **0**

Registration date
2021-04-22, 1400/02/02

Registrant information

Name
Mostafa Nematizad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4427 9498

Email address
mostafanemati73@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-20, 1399/11/01

Expected recruitment end date
2021-06-21, 1400/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the Efficacy and Safety of Colchicine plus

Methylprednisolone Pulse Therapy in Treatment of Covid-19 Patients with ARDS

Public title
Efficacy of Colchicine in Treatment of Covid-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with COVID-19 with moderate to severe respiratory failure admitted to ICU wards
Exclusion criteria:
Uncontrolled Diabetes Mellitus Active bacterial or viral (viral Hepatitis and HIV) or fungal infection Positive more than 0.5 Procalcitonin or positive bacterial and fungal culture of any specimen of body Sever Electrolyte disturbance History of severe reaction to Steroidal products Active Gastrointestinal bleeding
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method used in this study is the use of a table of random numbers
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants in this study, as well as outcome assessors, were kept blind
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
AJA University of Medical Sciences, Shahid Etemadzade Ave, West Fatemi Ave
City
Tehran
Province
Tehran
Postal code
1411718541
Approval date
2021-04-20, 1400/01/31
Ethics committee reference number
IR.AJAUMS.REC.1400.011

Health conditions studied

1

Description of health condition studied
Covid 19
ICD-10 code
B97.2
ICD-10 code description
Coronavirus as the cause of diseases classified elsewhere

Primary outcomes

1

Description
Evaluation of the efficacy of colchicine plus methylprednisolone pulse therapy in treatment of Covid-19 patients with Respiratory distress
Timepoint
During the hospitalization period
Method of measurement
According to measurement of secondary outcome variables

Secondary outcomes

1

Description
Duration of hospitalization in ICU
Timepoint
During the hospitalization period
Method of measurement
According to ICU hospitalization and discharge time

2

Description
Duration of being intubated
Timepoint
During the hospitalization period
Method of measurement
Period between intubation and extubation time

3

Description
Duration of staying in hospital
Timepoint
During the hospitalization period

Method of measurement
The difference between the time of admission and the time of discharge

4

Description
Patient's death
Timepoint
During the hospitalization period
Method of measurement
Based on patient file information

5

Description
SOFA score
Timepoint
During the hospitalization period
Method of measurement
Calculation based on defined table

Intervention groups

1

Description
Control group: Receiving standard treatment for patients who have ARDS due to covid19 disease including Dexamethasone (8mg daily till 10 days), Interferon beta1(250 microgram till 7 days) and Remdesivir (initial dose: 200mg then 100mg daily)
Category
Treatment - Drugs

2

Description
Intervention group: in addition to receiving standard treatment for patients who have ARDS due to covid19 disease, this group will receive Methylprednisolone pulse therapy (500mg each 12h until 3 days) and Colchicine pill (2mg stat then 1mg daily)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Ebrahim Hazrati
Street address
Imam Reza hospital - Etemadzadeh Ave - West Fatemi Street
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info@ajaums.ac.i
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https://imamreza.ajaums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Ebrahim Hazrati
Street address
AJA University of Medical Sciences, Shahid Etemadzade Ave, West Fatemi Ave
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Phone
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Fax
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Email
info@ajaums.ac.ir
Web page address
https://www.ajaums.ac.ir/
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

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Reza Mosaed

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Pharmacotherapy

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Person responsible for updating data

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Mostafa Nematizad

Position

Non-faculty general physician

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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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

It's 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