

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Ebrahim Hazrati

Street address

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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

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

Artesh University of Medical Sciences

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