

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Evaluation of the Effect of Methylene Blue with Supplements in the Treatment of Patients with Moderate to Severe Outpatient COVID-19 Infection in Comparison with the Control Group

#### Protocol summary

##### Study aim

Determining the effect of methylene blue with supplements on reducing the symptoms of hospitalization and mortality of patients with COVID virus 19 referred to the lung clinic

##### Design

A randomized, controlled trial, based on outpatients with COVID-19, which has two parallel groups.

##### Settings and conduct

COVID-19 patients with positive PCR or HRCT who refer to the lung clinic and are treated with methylene blue at standard dose / day (1mg /kg) and supplements

##### Participants/Inclusion and exclusion criteria

Inclusion Criteria: Outpatients with COVID-19 virus referred to a Lung Clinic Confirmed by HRCT or PCR; SPO2 without Mask after Ten Minutes between 70-96; Age Over 18 Years Old. Exclusion Criteria: Pregnancy; Severe Liver and Heart Disease; Acute Renal Failure Associated with the Need for Dialysis; Glucose 6-Phosphate Dehydrogenase Deficiency.

##### Intervention groups

COVID-19 outpatients treated with standard medical therapy (supportive therapy) and methylene blue and supplements

##### Main outcome variables

Oxygen Pressure Saturation; Respiratory Rate; Headache; Cough; Fever; Shivery; Respiratory Distress; Chest Pain Wall; Vomiting; Diarrhea; Hospital Stay; Mortality Rate after One Month

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220211053993N1**  
Registration date: **2022-05-28, 1401/03/07**

Registration timing: **prospective**

Last update: **2022-05-28, 1401/03/07**

Update count: **0**

##### Registration date

2022-05-28, 1401/03/07

##### Registrant information

###### Name

davood attaran

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3833 2746

###### Email address

attarand@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-06-22, 1401/04/01

##### Expected recruitment end date

2022-07-23, 1401/05/01

##### Actual recruitment start date

2022-06-22, 1401/04/01

##### Actual recruitment end date

2022-07-23, 1401/05/01

##### Trial completion date

2022-07-24, 1401/05/02

##### Scientific title

Evaluation of the Effect of Methylene Blue with Supplements in the Treatment of Patients with Moderate to Severe Outpatient COVID-19 Infection in Comparison with the Control Group

##### Public title

Evaluation of the Effect of Methylene Blue in the Treatment of Outpatients with COVID-19 Referred to the Lung Clinic

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Outpatients with COVID-19 virus referred to a Lung Clinic Confirmed by HRCT or PCR SPO2 without Mask after Ten Minutes between 70-96 Age Over 18 Years Old

##### **Exclusion criteria:**

Pregnancy Severe Liver and Heart Disease Acute Renal Failure Associated with the Need for Dialysis Glucose 6-Phosphate Dehydrogenase Deficiency

#### **Age**

From **18 years** old

#### **Gender**

Both

#### **Phase**

3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **240**

Actual sample size reached: **240**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

Randomization method: simple randomization, randomization unit: individual, randomization tool: by using the website of randomization: <https://www.random.org/lists/> Simple randomization is done by random numbers generated by the randomization site, according to the list produced, individuals will be randomly assigned to the intervention (methylene blue) or control groups.

#### **Blinding (investigator's opinion)**

Single blinded

#### **Blinding description**

In this single blind, the evaluator, who is a health care professional (nurse) and is responsible for collecting data (symptoms and hospitalization and mortality) from patients after using the drug, is not aware that each patient belongs to control group or intervention group.

#### **Placebo**

Not used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

#### **Street address**

Mashhad University of Medical Sciences, Daneshgah Avenue

#### **City**

Mashhad

#### **Province**

Razavi Khorasan

#### **Postal code**

91388-13944

#### **Approval date**

2022-02-26, 1400/12/07

#### **Ethics committee reference number**

IR.MUMS.REC.1400.344

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Covid-19

##### **ICD-10 code**

U07.1

##### **ICD-10 code description**

Covid-19

### **Primary outcomes**

#### **1**

##### **Description**

Oxygen pressure saturation

##### **Timepoint**

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

##### **Method of measurement**

Pulse oximeter

#### **2**

##### **Description**

Respiratory Rate

##### **Timepoint**

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

##### **Method of measurement**

Physical exam

#### **3**

##### **Description**

Headache

##### **Timepoint**

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

##### **Method of measurement**

Physical exam

#### **4**

##### **Description**

Cough

##### **Timepoint**

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

**Method of measurement**

Physical exam

**5**

**Description**

Shivery

**Timepoint**

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

**Method of measurement**

Physical exam

**6**

**Description**

Chest pain

**Timepoint**

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

**Method of measurement**

Physical exam

**7**

**Description**

Vomiting

**Timepoint**

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

**Method of measurement**

Physical exam

**8**

**Description**

Diarrhea

**Timepoint**

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

**Method of measurement**

Physical exam

**9**

**Description**

Fever

**Timepoint**

Interval time: the third day, the sixth day, the eleventh day, the fourteenth day after using Methylene Blue

**Method of measurement**

Physical exam

**Secondary outcomes**

**1**

**Description**

Hospital stay time

**Timepoint**

After 15 days

**Method of measurement**

Number of days

**2**

**Description**

Mortality rate

**Timepoint**

After 30 days

**Method of measurement**

Review of medical records

**Intervention groups**

**1**

**Description**

Intervention group: In addition to the standard treatment, Covid-19 outpatients are received orally methylene blue along with complementary materials two times per day in interval time 12 hours. The drug is used for 7 days until 14 days. Drug is prepared by Omid Rajabi pharmaceutical company. Methylene Blue (1 mg/Kg), Vitamin C, Glucose or sugar, Vitamine B1, B2, B3, Calcium Phosphate, Citrate Potassium, Carbonate Sodium, Glycine Amino Acid, Ginger, Lecithin, Ascorbyl Palmitate, Magnesium Stearate will be prepared as powder (in one sachet) and it will used orally after dissolving in water.

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: Patients will received just the standard treatment

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Pulmonary clinic- Dr Davod Ataran-Dr Saeed Hafizi

**Full name of responsible person**

Dr Soroush Attaran

**Street address**

between 1st and 3rd Besat Blvd

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176756697

**Phone**

+98 51 3882 8574

**Email**

attarand@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Majid Ghayour Mobarhan

**Street address**

Iman Reza Hospital, Daneshgah Avenue

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**Email**

GhayourM@mums.ac.ir

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

No

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Davood Attaran

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Qaem Hospital, Ahmadabad Avenue

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**Postal code**

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Dr Davood Attaran

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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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**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to

make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable