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 sacchet) 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

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Sponsors / Funding sources

1

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Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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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
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Other areas of specialty/work
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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
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