

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Application of Methylene Blue Along with Complementary Materials for Treatment of COVID-19 Outpatients with Less Than 8 Days from First Day of Clinical Symptoms

Protocol summary

Study aim

The determination of the effect of methylene blue along with complementary materials in decreasing the symptoms of disease, hospitalization and mortality in COVID-19 outpatients who referred to pulmonary 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 treatment with methylene blue (1 mg/kg/day) along with complementary materials

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Outpatients with COVID-19 referred to a lung clinic confirmed by HRCT or PCR. SPO2 is between 70-96 after taking off the mask. Age over 18 years old.
Exclusion Criteria: Pregnancy Severe impairment of liver and heart Renal insufficiency including severe renal impairment G6PD enzyme deficiency

Intervention groups

Covid-19 outpatients treated with standard medical therapy (supportive therapy) and methylene blue along with complementary materials

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: **IRCT20191228045924N2**
Registration date: **2021-11-22, 1400/09/01**
Registration timing: **prospective**

Last update: **2021-11-22, 1400/09/01**

Update count: **0**

Registration date

2021-11-22, 1400/09/01

Registrant information

Name

Daryoush Hamidi Alamdari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 8574

Email address

hamidiad@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-25, 1400/09/04

Expected recruitment end date

2022-01-20, 1400/10/30

Actual recruitment start date

2021-11-27, 1400/09/06

Actual recruitment end date

2022-01-20, 1400/10/30

Trial completion date

2022-02-19, 1400/11/30

Scientific title

Application of Methylene Blue Along with Complementary Materials for Treatment of COVID-19 Outpatients with Less Than 8 Days from First Day of Clinical Symptoms

Public title

Investigation of Methylene Blue for treatment of COVID-19 outpatients referred to pulmonary clinic.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Outpatient COVID-19 patients who confirmed by PCR or HRCT referred to pulmonary clinic SPO2 is between 70-96 after taking off the mask

Exclusion criteria:
Pregnancy Severe impairment of liver and heart Renal insufficiency including severe renal impairment G6PD enzyme deficiency

Age
From **18 years** old

Gender
Both

Phase
4

Groups that have been masked

- Outcome assessor

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

Ave

City
Mashhad

Province
Razavi Khorasan

Postal code
91388-13944

Approval date
2021-11-06, 1400/08/15

Ethics committee reference number
IR.MUMS.REC.1400.243

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
COVID-19,

ICD-10 code description
U07.1

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

Control 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 Saeid Hafizi

Full name of responsible person

Dr. Daryoush Hamidi Alamdari

Street address

Iman Reza Hospital, Daneshgah Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayour Mobarhan

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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. Daryoush Hamidi Alamdari

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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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