Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 51 3882 8574

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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 sacchet) 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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Person responsible for updating data

Contact

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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