

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation the Effects of Methylene Blue on Coronavirus Patients treatment

Protocol summary

Study aim

Determining the effectiveness of Methylene Blue on treatment of the Coronavirus Patients in Chaharmahal Va Bakhtiari province

Design

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

Settings and conduct

Shahrekord university of medical sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with no underlying disorders, Patients who are free of any kidney (creatinine test), liver (liver and LFT tests), and heart (echocardiography) damage . The age of inclusion in the study is 20-50 years. Nasopharyngeal RT-PCR test sample is to be positive. Patients are to have lung damage scanned through CT scan. patients are to have no history of viral infections with hepatitis and AIDS. Patients are to not have received recombinant treatments. Patients are to not have G6PD enzyme defect. O2Saturation of patients is to be less or equal to 85. Exclusion: Pregnant women and women who are planning to become pregnant. Breastfeeding women. People with a history of allergies to methylene blue. People with a BMI above 30. People with kidney, heart, lung disorders.

Intervention groups

Treatment group: O2Saturation < 85 (30 patients)
Control group: O2Saturation < 85 (30 patients)

Main outcome variables

Methylene blue; Corona virus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211012052735N1**

Registration date: **2021-11-05, 1400/08/14**

Registration timing: **prospective**

Last update: **2021-11-05, 1400/08/14**

Update count: **0**

Registration date

2021-11-05, 1400/08/14

Registrant information

Name

Javad Saffari-Chaleshtori

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38 3224 3587

Email address

saffari.j@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-11, 1400/08/20

Expected recruitment end date

2021-12-11, 1400/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the Effects of Methylene Blue on Coronavirus Patients treatment

Public title

Effect of Methylene Blue in treatment of Coronavirus Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients are to be free of any underlying disorders.
Patients are to be free of any kidney (creatinine test), liver (liver and LFT tests), and heart damages. The age of inclusion in the study is to be between 20-50 years
Nasopharyngeal RT-PCR test sample is to be positive
Diagnosed with lung damages through CT scan
Have no history of viral infections with hepatitis and AIDS
Have not had received recombinant treatments
Have not had G6PD enzyme defect
O2 Saturation of patients is to be less or equal to 85

Exclusion criteria:

Pregnant women and women who are planning to become pregnant
Breastfeeding women
People with a history of allergies to methylene blue
People with a BMI above 30
People with kidney, heart, lung disorders

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: simple randomization
randomization unit: individualized randomization tool:
through the randomization website
<https://random.org/lists/>. Simple randomization will be achieved through numbers randomly generated by the website, in a way that according to the generated list, the target individuals will be randomly divided into two groups of control and treatment (by Methylene blue)

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients, Researchers, Health personnel, data collectors, and those evaluating the outcome will be blinded throughout this study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

IR.SKUMS.REC.1400.111

Street address

Rahmatyeh

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8813833435

Approval date

2021-08-14, 1400/05/23

Ethics committee reference number

IR.SKUMS.REC.1400.111

Health conditions studied

1

Description of health condition studied

coronavirus infection

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Blood O2 saturation

Timepoint

daily

Method of measurement

saturation %

Secondary outcomes

empty

Intervention groups

1

Description

In this clinical trial study, 60 patients with Covid-19 admitted to Hajar Hospital in Shahrekord with positive PCR test and O2-Saturation equal to 85 and less are selected and randomly divided into two groups of 30. Control and Intervention. Treated group: O2-Saturation equal to 85 and less. All the 30 patients will be matched in terms of age and gender. Prior to the study, all patients will be tested for biochemical factors such as CRP, methemoglobin, ferritin, serum creatinine, SGOT, SGPT, and LDH, Ddimer, CRP, and O2-Saturation levels will be measured daily. For patients in the treatment group, methylene blue (at the time of hospitalization) with a concentration of 34 mg / kg is given for 4 days,

orally, along with the conventional treatments (routine treatment), Remdesiver and corticosteroids. At the end of four days, patients are assessed for improvement in indicators (general condition, O2-Saturation level, and biochemical factors) compared to the control group.

Category

Treatment - Drugs

2**Description**

In this clinical trial study, 60 patients with Covid 19 admitted to Hajar Hospital in Shahrekord with positive PCR test and O2-Saturation equal to 85 and less are selected and randomly divided into two groups of 30. Control group:O2-Saturation equal to 85 and less. The 30 patients in both groups will be matched in terms of age and gender. Prior to the study, all patients will be tested for biochemical factors such as CRP, methemoglobin, ferritin, serum creatinine, SGOT, SGPT, and LDH, Ddimer, CRP, and O2-Saturation levels are measured daily. The control group will only receive the usual treatment (routine treatment) of Remdesiver and corticosteroids with placebo. At the end of four days, patients are assessed for improvement in indicators (general condition, O2-Saturation level, and biochemical factors).

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahrekord Hajar Hospital

Full name of responsible person

Dr. Akbar Soleimani

Street address

Rahmatieh

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Shahrekord

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Chahar-Mahal-va-Bakhtiari

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8813833435

Phone

+98 38 3333 1471

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr Mehraban Sadeghi

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

Shahre-kord 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**

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr Akbar Soleimani

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Subspecialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be shared

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Provide other scientific research

From where data/document is obtainable

Dr Akbar Soleimani

What processes are involved for a request to access data/document

By E-mail

Comments