

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 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

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8813833435

**Phone**

+98 38 3333 1471

**Email**

j\_saffari@yahoo.com

**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**

Rahmatyeh

**City**

Shahrekord

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Chahar-Mahal-va-Bakhtiari

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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

**Street address**

Rahmatyeh

**City**

Shahrekord

**Province**

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**Postal code**

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**Person responsible for scientific 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 updating data**

**Contact**

**Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Dr. Akbar Soleimani

**Position**

Associate professor

**Latest degree**

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**Other areas of specialty/work**

Internal Medicine

**Street address**

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**City**

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**Email**

j\_saffari@yahoo.com

**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**