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
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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 O2Saturation 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr Mehraban Sadeghi
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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

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Person responsible for updating data

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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