Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Evaluation of the efficacy and safety of methylene blue administration for treatment of COVID-19 patients

Protocol summary

Study aim
The aim of this study is to investigate the effect of methylene blue along with vitamin C and N-acetyl cysteine in the treatment of COVID 19 patients

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

Settings and conduct
Imam Reza Hospital confirmed case of Covid-19 by RT-PCR on the nasopharyngeal swab collected or clinical and HR-CT features Treatment with methylene blue (1 mg/kg) along with vitamin C 250 (mg/daily) and N-acetyl cysteine 2 gr/daily

Participants/Inclusion and exclusion criteria
Inclusion criteria: Confirmed case of Covid-19 (by RT-PCR, HRCT) Admission to the intensive care unit Need for intubation and mechanical ventilation (PaO2/FiO2 < 100-200) Written informed consent Exclusion criteria: Age less than 18 years old Pregnancy History of renal diseases, heart diseases Cirrhosis, active chronic hepatitis The history of G6PDH deficiency Severe renal failure

Intervention groups
Covid-19 patients treated with standard medical therapy (supportive therapy). Covid-19 patients treated with mixture of MCN (Methylene blue, vitamin C, N-acetyl cysteine).

Main outcome variables
The respiratory rate- The oxygen saturation - The hospital stay- The mortality rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191228045924N1**
Registration date: **2020-09-20, 1399/06/30**
Registration timing: **retrospective**
Last update: **2020-09-20, 1399/06/30**
Update count: **0**

Registration date
2020-09-20, 1399/06/30

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
2020-04-19, 1399/01/31

Expected recruitment end date
2020-08-20, 1399/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the efficacy and safety of methylene blue administration for treatment of COVID-19 patients

Public title
Effect of methylene blue on treatment of COVID-19 patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmed case of Covid-19 (by RT-PCR, HRCT) Admission to intensive care unit Need for intubation and mechanical ventilation (PaO2/FiO2 < 100-200) Written informed consent

Exclusion criteria:

Pregnancy and breastfeeding G6PDH deficiency Severe renal insufficiency (glomerular filtration rate <30 mL/min/1.73m2) Active chronic hepatitis Severe hepatic disease defined by GOT or GPT levels three times above the normal upper limit Patients with history of allergic reaction or significant sensitivity to methylene blue Treatment with immunosuppressive agents Use of other investigational drugs in the moment of inclusion

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

www.clinicaltrial.gov

Secondary trial Id

NCT04370288

Registration date

2020-04-30, 1399/02/11

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

2020-04-19, 1399/01/31

Ethics committee reference number

IR.MUMS.REC.1399.122

Health conditions studied

1

Description of health condition studied

Covid-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, Treatment

Primary outcomes

1

Description

Saturated pressure oxygen (SPO2)

Timepoint

Third day, fifth day, tenth day

Method of measurement

Pulse micrometre

2

Description

Respiratory rate in one minute

Timepoint

Third day, fifth day, tenth day

Method of measurement

Physical exam

Secondary outcomes

1

Description

Mortality rate in both groups

Timepoint

Day 28

Method of measurement

Review of medical records

2

Description

Hospital stay

Timepoint

At the beginning of the study and the end of the trial

Method of measurement

Number of days

Intervention groups

1

Description

Intervention group: Covid-19 patients treated with methylene blue, vitamin C, N-acetyl cysteine. Treatment with methylene blue (60mg/daily) along with vitamin C 250 (mg/daily) and N-acetyl cysteine 2 gr/daily. These drugs are used for 7 days until 14 days. Methylene blue will be prepared by Omid Rajabi pharmaceutical company, Mashhad. Vitamin C will be prepared by Jalinous pharmaceutical company, Tehran. N-acetylcysteine will be prepared by Osve pharmaceutical company, Tehran.

Category

Treatment - Drugs

2

Description

Control group: Covid-19 patients treated with standard medical therapy (supportive therapy). Standard medical therapy is done for patients according to the Health Ministry instruction which WHO sends for the Health Ministry.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

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 Mohsen Tafaghodi

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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

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

Daryoush Hamidi Alamdari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Person responsible for scientific inquiries

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Associate professor

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Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
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Ph.D Student

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Master

Other areas of specialty/work
Biochemistry

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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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
All data related to the project after unidentifiable of people will be shared.

When the data will become available and for how long
Access to data are allowed 6 months after the publication of results.

To whom data/document is available
Our data will be available for university staffs and academic institutions.

Under which criteria data/document could be used
All types of analysis for data are allowed by authorized researchers.

From where data/document is obtainable
hamidiad@mums.ac.ir

What processes are involved for a request to access data/document
Accept permission from the project implementer for the applicant

Comments