

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Evaluation of therapeutic effects of Metronidazole In Inpatients with Pneumonia Due to COVID-19

Protocol summary

Study aim

Determination of therapeutic effects of Metronidazole In Inpatients with Pneumonia Due to COVID-19

Design

Clinical trial with control group, single-blind, randomized, phase 2 on 15 patients and will follow for 7 days. Inpatient admission dates will be used for randomization.

Settings and conduct

This pilot randomized single-blind clinical trial will be performed in Shohada Goharshahi hospital on patients after obtaining permission from the ethics committee on patients with pneumonia caused by the COVID-19, who are on antiviral medication according to national protocol. Patients will be divided into two groups. Intervention group will be treated with metronidazole 250 mg every 6 hours. Laboratory and clinical symptoms will be evaluated every 7 days. The data will be analyzed by SPSS software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hospitalized patients with COVID-19 pneumonia. COVID-19 infection should be confirmed by RT-PCR or lung CT scan. Both genders. Age ≥ 18 years at time of signing Informed Consent Form. Willing and able to provide written informed consent prior to performing study to any assigned treatment arm. Must agree not to enroll in another study of an investigational agent prior to completion of study. Exclusion criteria: Known allergic reaction to metronidazole. Pregnant or breastfeeding, or positive pregnancy test.

Intervention groups

Patients with pneumonia due to COVID-19 will receive Standard of care treatment according to the national guidelines. Intervention group will receive metronidazole 250 every 6 hours. In addition to standard treatment and control group will not receive metronidazole.

Main outcome variables

O2 Saturation, Length of hospital stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200608047686N1**

Registration date: **2020-06-30, 1399/04/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-30, 1399/04/10**

Update count: **0**

Registration date

2020-06-30, 1399/04/10

Registrant information

Name

Muhanna Kazempour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5541 7243

Email address

muhanakazempour@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-31, 1399/03/11

Expected recruitment end date

2020-07-01, 1399/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effects of Metronidazole In Inpatients with Pneumonia Due to COVID-19	
Public title	The role of metronidazole in COVID-19
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Inpatients with Pneumonia Due to COVID-19
Exclusion criteria:	Hypersensitivity Reactions to Metronidazole Pregnancy
Age	From 18 years old
Gender	Both
Phase	2
Groups that have been masked	Participant
Sample size	Target sample size: 30
Randomization (investigator's opinion)	Randomized
Randomization description	simple randomization
Blinding (investigator's opinion)	Single blinded
Blinding description	After signing the consent form, According to the admission date of hospitalized patients with pneumonia due to COVID-19, Participants are randomly assigned to intervention or control groups and they are not aware of the group to which they are allocated.
Placebo	Not used
Assignment	Parallel
Other design features	According to the admission date of hospitalized patients with pneumonia due to COVID-19, Participants are randomly assigned to intervention or control groups and they are not aware of the group to which they are allocated. The "intervention group" receives national standard treatment in addition to metronidazole, and the "control group" receives standard treatment.
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics committee of Shahid beheshti University of Medical Sciences
Street address	Yaman St, Velenjak, Shahid Chamran Highway

City	Tehran
Province	Tehran
Postal code	19857-17443
Approval date	2020-05-30, 1399/03/10
Ethics committee reference number	IR.SBMU.RETECH.REC.1399.157
Health conditions studied	
<u>1</u>	
Description of health condition studied	COVID-19
ICD-10 code	U07.1
ICD-10 code description	COVID-19
Primary outcomes	
<u>1</u>	
Description	O2 Saturation
Timepoint	within 7 days from initiation of study treatmentat
Method of measurement	Pulse Oximetry
Secondary outcomes	
<u>1</u>	
Description	Lenght of hospitat stay
Timepoint	daily up to discharge
Method of measurement	Inpatient days
<u>2</u>	
Description	Mortality
Timepoint	daily up to death during hospitalizatiion
Method of measurement	Patient death
Intervention groups	
<u>1</u>	
Description	Intervention group: 15 eligible patients with moderate to severe COVID-19 in a 1:1 ratio compared to the control group who receive 250 mg metronidazole tablets orally

every 6 hours for 7 days in addition to the standard treatment.

Category

Treatment - Drugs

2

Description

Control group: 15 eligible patients with moderate to severe COVID-19 disease who receive national standard treatment for COVID-19.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Gornam Hospital

Full name of responsible person

Muhanna Kazempour

Street address

Shahid Mohammad Reza Azam Erfani St, Khorasan Square

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1794694616

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shgm-hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Yaman St, Velenjak St, Shahid Chamran Highway

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Muhanna Kazempour

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Loghman Hakim Hospital, Kamali Ave, South Kargar St

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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

Associate professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity
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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

Yes - There is 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

At the time of publication

When the data will become available and for how long

At the time of publication

To whom data/document is available

Public

Under which criteria data/document could be used

They will be publically available.

From where data/document is obtainable

The study protocol, statistical analytic plan informed consent forms will be shared as supplementary material at the time of publication of results.

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

The study protocol, statistical analytic plan informed consent forms will be shared as supplementary material at the time of publication of results.

Comments