# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Nov 2026

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

### Protocol summary

**Study aim**
Determination of therapeutic effects of Metronidazole In Inpatients with Pneuomonia Due to COVID-19

**Design**
Clinical trial with control group, single-blind, randomized, phase 2 on 15 patients and will followe 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 gomnam hospital on patients after obtaining permission from the ethics committee on patients with pneumonia caused by the COVOID-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 COVOID-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 pneuomonia due to COVOID-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 receive metronidazole.

**Main outcome variables**
O2 Saturation, Lenght of hospitat 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**
muhannakazempour@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 Pneuomonia Due to COVID-19

**Public title**
The role of metronidazole in COVID-19
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Inpatients with Pneuomonia 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

### 1

**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

### 1

**Description of health condition studied**
COVID-19
**ICD-10 code**
U07.1
**ICD-10 code description**
COVID-19

## Primary outcomes

### 1

**Description**
O2 Saturation
**Timepoint**
within 7 days from initiation of study treatmentat
**Method of measurement**
Pulse Oximetry

## Secondary outcomes

### 1

**Description**
Lenght of hospitat stay
**Timepoint**
daily up to discharge
**Method of measurement**
Inpatient days

### 2

**Description**
Mortality
**Timepoint**
daily up to death during hospitalizatiion
**Method of measurement**
Patient death

## Intervention groups

### 1

**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 Gomnam Hospital

**Full name of responsible person**

Muhanna Kazempour

**Street address**

Shahid Mohammad Reza Azam Erfani St, Khorasan Square

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**Email**

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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**Postal code**

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**Phone**

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**Email**

info@sbmu.ac.ir

**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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muhannakazempour@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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Muhanna Kazempour

**Position**

Associate professor

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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**
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**