Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 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)

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+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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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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

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Person responsible for scientific inquiries

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Full name of responsible person

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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