Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the efficacy and safety of inhaled magnesium sulfate in combination with standard treatment in Covid-19 patients: a clinical trial

Protocol summary

Study aim

1-Evaluation of the efficacy and safety of inhaled magnesium sulfate in combination with standard treatment in COVID-19 patients.

Design

Randomized controlled clinical trial, with intervention and control groups, without blinding, randomized, phase 3 per 100 patients, randomized by Permuted block randomization

Settings and conduct

This study is a prospective, not-blinded, randomized controlled clinical trial and will be performed on on 100 patients aged 18 to 80 years, in Masih Daneshvari Hospital in Tehran, Shahid Labbafinejad hospital in Tehran and Shahid Sadoughi Hospital in Yazd. Patients are randomly divided into two intervention groups in and control group . At the beginning of the study, patients will be randomly assigned to one of two divided groups (50 people in each group) by permutation block method. Patients in the intervention group receive magnesium sulfate by inhalation (5 cc of a 20% injectable vial or 2 cc of a 50% injectable vial will be diluted by 50 cc distilled water and nebulized via a nebulizer with oxygen mask) in addition to standard treatment. Patients in the control group also receive standard treatment. groups of 50 control or intervention.

Participants/Inclusion and exclusion criteria

Minimum age 18 and maximum age 80 years, Candidate for hospitalization, Signing up the informed consent form The first 24 to 48 hours of hospitalization ؛Patients with heart block, Patients with myocardial injury.

Intervention groups

Intervention group: includes 50 patients who receive magnesium sulfate inhaled (5 cc of 20% injectable vial or 2 cc of 50% injectable vial) every 8 hours for 5 days along with standard treatment. Control group: includes 50 patients who receive standard treatment.

Main outcome variables

Improve respiratory symptoms including shortness of breath, cough; oxygen saturation

General information

Reason for update

1-Correction two numbers in the description of how to randomize - English 2-Correction expected recruitment start date and Correction expected recruitment end date

Acronym

IRCT registration information

IRCT registration number: **IRCT20191211045691N1**
Registration date: **2020-07-28, 1399/05/07**
Registration timing: **prospective**

Last update: **2021-01-05, 1399/10/16**
Update count: **4**

Registration date

2020-07-28, 1399/05/07

Registrant information

Name

Seyed Ruhollah Mousavinasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4332

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-30, 1399/05/09

Expected recruitment end date

2021-02-28, 1399/12/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the efficacy and safety of inhaled magnesium sulfate in combination with standard treatment in Covid-19 patients: a clinical trial

Public title
Evaluation of the efficacy and safety of inhaled magnesium sulfate in combination with standard treatment in Covid-19 patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Minimum age 18 and maximum age 80 years Candidate for hospitalization (o2sat<93% ؛ RR>24 ؛ Pao2/Fio2<300) The first 24 hours or 48 hours of hospitalization Signing up the informed consent form
Exclusion criteria:
Patients with heart block Patients with myocardial injury
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization (quadruple blocks) All possible blocks are arranged as follows: block 1: ABAB block 2: AABB block 3: ABBA block 4: BBAA block 5: BABA block 6: BAAB We need 25 blocks to select 100 people. We randomly select these blocks from the numbers 1 to 6.Using R software, we choose a random number between the numbers 1 to 6. For example, number 6 is chosen as the first block and number 2 as the forth block. The people who enter the study are given B-A-A-B-A-A-B-B, respectively. Finally, group A receives control intervention and group B receives treatment intervention
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Research Institute of Tuberculosis and Lung Diseases(NRITLD), Masih Daneshvari Hospital
Street address
Tehran, Shahid Bahonar St. (Niavaran), Darabad, National Research Institute of Tuberculosis and Lung Diseases Masih Daneshvari Hospital
City
Tehran
Province
Tehran
Postal code
1956944413
Approval date
2020-07-26, 1399/05/05
Ethics committee reference number
IR.SBMU.NRITLD.REC.1399.148

Health conditions studied

1

Description of health condition studied
Covid-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Improve respiratory symptoms including shortness of breath and cough
Timepoint
Days 1 to 5 and at the end of the first week
Method of measurement
Questionnaire

2

Description
Blood o2 saturation
Timepoint
Just before and 1 hour after prescribe medication
Method of measurement
Pulse oximetry device

Secondary outcomes

1

Description
C-reactive protein

Timepoint
C-reactive protein is measured daily for days 1 to 5.
Method of measurement
Measurement of C-reactive protein is performed by a laboratory sample of blood taken from the patient.

2

Description
Total number of lymphocytes.
Timepoint
The total number of lymphocytes is measured daily for days 1 to 5.
Method of measurement
Measurement of The total number of lymphocytes is performed by a laboratory sample of blood taken from the patient.

3

Description
D-dimer test
Timepoint
The D-dimer test is measured daily for days one to five
Method of measurement
The D-dimer test is performed with a blood sample taken from the patient by a laboratory

4

Description
Ferritin
Timepoint
Ferritin is measured daily for days 1 to 5.
Method of measurement
Measurement of ferritin is performed by a laboratory sample of blood taken from the patient

Intervention groups

1

Description
Intervention group: includes 50 patients who receive magnesium sulfate inhaled (5 cc of a 20% injectable vial or 2 cc of a 50% injectable vial will be diluted by 50 cc distilled water and nebulized via a nebulizer with oxygen mask) along with standard treatment.
Category
Treatment - Drugs

2

Description
Control group: includes 50 patients who receive standard treatment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
National Research Institute of Tuberculosis and Lung Diseases(NRITLD), Masih Daneshvari Hospital
Full name of responsible person
Guitti Pourdowlat
Street address
Tehran, Shahid Bahonar St. (Niavaran), Darabad, National Research Institute of Tuberculosis and Lung Diseases Masih Daneshvari Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
National Research Institute of Tuberculosis and Lung Diseases(NRITLD), Masih Daneshvari Hospital
Full name of responsible person
Parissa Farnia
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
National Research Institute of Tuberculosis and Lung Diseases(NRITLD), Masih Daneshvari Hospital

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
Guitti Pourdowlat
Position
Assistant 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

Contact
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Seyed Ruhollah Mousavinasab
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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

Research proposal and clinical study results

When the data will become available and for how long

After official publication in medical journals

To whom data/document is available

Those who refer to medical journals

Under which criteria data/document could be used

After official publication in medical journals

From where data/document is obtainable

Refer to medical journals, Email to the corresponding author and principal investigator

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

Email to the corresponding author and principal investigator

Comments