

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 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)

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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 ($SpO_2 < 93\%$ \downarrow RR > 24 \downarrow 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 fourth 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

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Province

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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

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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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Tehran, Shahid Bahonar St. (Niavaran), Darabad, National Research Institute of Tuberculosis and Lung Diseases Masih Daneshvari Hospital

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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

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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**Contact****Name of organization / entity**National Research Institute of Tuberculosis and Lung
Diseases(NRITLD), Masih Daneshvari Hospital**Full name of responsible person**

Guitti Pourdowlat

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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National Research Institute of Tuberculosis and Lung
Diseases Masih Daneshvari Hospital**City****Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Ruhollah Mousavinasab

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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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 PlanUndecided - 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 CodeUndecided - 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