Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Clinical trial of lithium in improving the clinical and laboratory symptoms of patients with COVID-19

Protocol summary

Study aim
Evaluation the effect of lithium carbonate in covid-19 patients

Design
A randomized, blinded, placebo controlled clinical trial with a parallel group design of 40 patients, randomizing with the table of random numbers.

Settings and conduct
This study will be performed on outpatients. In this study, 40 patients with covid-19 disease were selected and randomly assigned to two groups of 20 individuals. Patients in the standard diet control group will receive standard coronavirus treatment with placebo. In addition to the standard diet, patients in the treatment group will be treated with 300-900 mg/day of lithium carbonate for at least 2 weeks. Patients are monitored at intervals of 3 days, 1 week and 2 weeks after receiving the drug or placebo in terms of time interval until clinical and laboratory symptoms improve.

Participants/Inclusion and exclusion criteria
People aged 18-65 years old with a diagnosis of coronavirus based on clinical and laboratory symptoms;home quarantine and outpatients

Intervention groups
The control group receives standard anti-coronavirus drugs with placebo. In addition to the common anticorona drugs, the treatment group also receives lithium carbonate.

Main outcome variables
Time interval until lymphopenia improves, Time interval until CRP normalizes, Time interval until clinical symptoms improve (fever, cough and myalgia)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20081019001369N5**
Registration date: **2020-04-26, 1399/02/07**
Registration timing: **prospective**

Last update: **2020-04-26, 1399/02/07**
Update count: **0**

Registration date
2020-04-26, 1399/02/07

Registrant information

Name
Hossein Hosseinzadeh

Name of organization / entity

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Iran (Islamic Republic of)

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+98 51 3180 1193

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-02, 1399/02/13

Expected recruitment end date
2020-07-22, 1399/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial of lithium in improving the clinical and laboratory symptoms of patients with COVID-19

Public title
Effect of lithium carbonate on COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with covid-19 symptoms Indication of home quarantine outpatients aged range 18-65 uears old

Exclusion criteria:

Patients connected to acatheter or under chemotherapy Patients taking cytotoxic drugs or corticosteroids Patients having a psychological problem now or in the past or with a history of psychological problem in first class family Patients who used cigarette at least one month before the study

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in three stages: 1- Random sequence generation: this step simple or limited randomization will be done based on a table of random numbers 2- Allocation concealment: which is done in the form of coded boxes (numbered drug containers) with a random sequence. In this method, a number of boxes with the same shape and size are numbered based on random sequences and contain drugs or placebo that have a completely similar appearance. 3- Execution of random allocation process: A: Identify the person who creates the random sequence B: A person who evaluates and registers researchers in terms of inclusion and exclusion criteria C: The person who assigned the participants to the groups: infectious diseases specialist The main researcher of the project, who creates a random sequence, does not interfere in other stages of randomization, including registration and allocation of participants, and the person involved in creating a random program is separate from other researchers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug and placebo are given as a same-color and –size tablets in boxes labeled with the letters A and B in box. The medical staff, the patient and the data collector are not aware of the nature of the drug or placebo, and only the executor of research project is aware of the nature of the contents of the two kind of tablets.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical Ethics Committee of Mashhad University of Medical Sciences

Street address

Blv.Vakilabad 2- School of Pharmacy-1365-91775

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948954

Approval date

2020-04-23, 1399/02/04

Ethics committee reference number

IR.MUMS.REC.1399.145

Health conditions studied

1

Description of health condition studied

covid-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19 Disease

Primary outcomes

1

Description

Time interval until clinical symptoms improve

Timepoint

3 days, 1 week and 2 weeks after treatment

Method of measurement

time of recovery

Secondary outcomes

1

Description

Fever

Timepoint

3 days, 1 week and 2 weeks after treatment

Method of measurement

Thermometer

2

Description
lymphopenia
Timepoint
3 days, 1 week and 2 weeks after treatment
Method of measurement
Cell counter device

3

Description
CRP
Timepoint
3 days, 1 week and 2 weeks after treatment
Method of measurement
CRP kit

Intervention groups

1

Description
Intervention group: In addition to the standard treatment regimen for COVID-19, the lithium carbonate tablets (300 mg/day to 900 mg/day) will be given for 2 weeks.
Category
Treatment - Drugs

2

Description
Control group: Patients on the standard treatment regimen for COVID-19 will receive placebo tablets once a day for 2 weeks. The placebo is formulated in tablets of the same shape and size as the drug tablets and contains inert agents.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hasheminejad Hospital
Full name of responsible person
Javad Dehghan Nayyeri
Street address
Mofateh boulevard, Vahid street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Hossein Hosseinzadeh
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Pharmacology
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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

Not applicable