

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Oct 2020

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

Country

Iran (Islamic Republic of)

Phone

+98 51 3180 1193

Email address

hosseinzadehh@mums.ac.ir

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 years 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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9137913316

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DehghanMJ@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

Daneshgah St.

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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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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

Professor

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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