

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Double-blind placebo-controlled clinical trial of evaluating the effectiveness of Ivermectin in treatment of outpatients with COVID-19 in 2021

Protocol summary

Study aim

Determining the effect of ivermectin on PCR test, clinical improvement, percentage and duration of hospitalization in outpatients with COVID-19

Design

Clinical trial with control group, parallel groups, double-blind, randomized, phase 3 on 1000 patients. Patients are divided into two groups by a simple randomization method with a table of random numbers. The control group will receive standard and placebo treatment and the intervention group will receive Ivermectin for three days in addition to the standard treatment.

Settings and conduct

COVID-19 positive rapid test patients referred to family physician and infectious disease specialist are divided into two groups of intervention and control. The present study is double-blind so that patients and physicians will be unaware of how the intervention and control groups are assigned.

Participants/Inclusion and exclusion criteria

Patients with COVID-19 positive rapid test or RT-PCR age >5 years and weight >15 kg are included in the study

Intervention groups

The intervention group will use Iranian standard treatment protocol for COVID-19 in addition to Ivermectin 6 mg oral tablet at a dose of 0.4 mg/kg manufactured by Alborz Daru Co of Iran for 3 days as follows: weight 15-24, 6 mg; Weight 35-25, 12 mg; Weight 50-36, 18 mg; Weight 80-5, 24 mg and weight over 80, 0.4 mg/kg

Main outcome variables

The primary endpoints are clinical improvement and negative PCR result after 6 days. Clinical improvement is defined as reduction in persistent cough (more than one hour of excessive coughing, or 3 periods of coughing in 24 hours that disrupts daily life and ability to work) and tachypnea and O2 saturation above 94%.

General information

Reason for update

Increase in sample size

Acronym

IRCT registration information

IRCT registration number: **IRCT20111224008507N4**

Registration date: **2021-01-31, 1399/11/12**

Registration timing: **prospective**

Last update: **2021-03-06, 1399/12/16**

Update count: **1**

Registration date

2021-01-31, 1399/11/12

Registrant information

Name

Mohammad Sadegh Rezai

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3334 2334

Email address

rezai@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double-blind placebo-controlled clinical trial of evaluating the effectiveness of Ivermectin in treatment of outpatients with COVID-19 in 2021

Public title

Evaluation of the effect of Ivermectin in treatment of outpatients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with positive coronavirus rapid test or RT-PCR positive No need for hospitalization Weight >15 kg Age >5 years No treatment with antiviral drugs before and during the study Informed consent for inclusion

Exclusion criteria:

Underlying liver and kidney disease Patients with acquired immunodeficiency Pregnancy and lactation

Age

From 5 years old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: 1000

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to two groups of intervention and control with 500 members using block randomization with block sizes of 4. Randomization will be done using the software randomization option in Excel. The randomization process is performed by the study methodology consultant and clinical researchers are not aware of the randomization process.

Blinding (investigator's opinion)

Double blinded

Blinding description

After selecting the samples, none of the participant will be aware of randomization and allocation to groups. Physicians are given a table of pre-coded numbered numbers and patients are entered into the study in order of table numbers. Therefore, the present study is double-blind. Ivermectin and placebo tablets are the same shape, color and size and are delivered to the patient/parents in a package.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Vice chancellor for Research, Moallem square, Sari

City

Sari

Province

Mazandaran

Postal code

4815838477

Approval date

2020-12-30, 1399/10/10

Ethics committee reference number

IR.MAZUMS.REC.1399.869

Health conditions studied

1

Description of health condition studied

COVID-19 infection

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Clinical improvement

Timepoint

Daily until improvement

Method of measurement

Clinical improvement is defined as reduction in persistent cough (more than one hour of excessive coughing, or 3 periods of coughing in 24 hours that disrupts daily life and ability to work) and tachypnea and O2 saturation above 94%.

2

Description

Negative PCR result

Timepoint

6 days after intervention

Method of measurement

RT-PCR

Secondary outcomes

1

Description

The main complaints recovery time

Timepoint

Daily until symptoms resolve

Method of measurement

Checklist containing patient complaints

2

Description

Need to be hospitalized

Timepoint

Daily until hospitalization or improvement

Method of measurement

Percentage of hospitalization and the interval from the beginning of the intervention to hospitalization

3

Description

Mortality

Timepoint

Daily

Method of measurement

Record in checklist

4

Description

Drug side effect

Timepoint

Daily

Method of measurement

Wheezing, itching, skin rash, edema, and hypotension are assessed daily

Intervention groups

1

Description

Intervention group: The intervention group will use Iranian standard treatment protocol for COVID-19 in addition to Ivermectin 6 mg oral tablet at a dose of 0.4 mg/kg manufactured by Alborz Daru Co, Iran for 3 days as follows: weight 15-24, 6 mg; Weight 35-25, 12 mg; Weight 50-36, 18 mg; Weight 80-5, 24 mg and weight over 80, 0.4 mg/kg

Category

Treatment - Drugs

2

Description

Control group: In the control group, placebo tablets made by Alborz Daru company of Iran with the same shape, color and weight based dose of ivermectin will be used for three days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Office of family physicians and infectious disease specialists and pediatric infectious diseases sub

Full name of responsible person

Dr Mohammad Sadegh Rezai

Street address

Bouali Hospital, Pasdaran boulevard, Sari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Majid Saeidi

Street address

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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

Mazandaran 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**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Sadegh Rezai

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Infectious diseases

Street address

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Fatemeh Hosseinzadeh

Position

Officer

Latest degree

Master

Other areas of specialty/work

Psychology

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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

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Part of the data is accessible

When the data will become available and for how long

Starting in January 2022

To whom data/document is available

Everybody

Under which criteria data/document could be used

Systematic review articles

From where data/document is obtainable

Contact Dr. Mohammad Sadegh Rezai. E-mail:

drmsrezai@yahoo.com

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

After contact, information is sent within a few days

Comments