

# 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

##### City

Sari

##### Province

Mazandaran

##### Postal code

4815838477

##### Phone

+98 11 3334 2334

##### Email

drmsrezai@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

Dr. Majid Saeidi

##### Street address

Vice chancellor for Research, Moallem square, Sari

##### City

Sari

##### Province

Mazandaran

##### Postal code

4712855689

##### Phone

+98 11 3334 2334

##### Email

msaeidi@mazums.ac.ir

#### 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**

Bouali Hospital, Pasdaran boulevard, Sari

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815838477

**Phone**

+98 11 3334 2334

**Email**

drmsrezai@yahoo.com

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

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr. Mohammadsadegh Rezai

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Infectious diseases

**Street address**

Bouali Hospital, Pasdaran Boulevard, Sari

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815838477

**Phone**

+98 11 3334 2334

**Email**

drmsrezai@yahoo.com

**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

**Street address**

Bouali Hospital, Pasdaran Boulevard, Sari

**City**

Sari

**Province**

Mazandaran

**Postal code**

4815838477

**Phone**

+98 11 3334 2334

**Email**

fatima.hzade@gmail.com

**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**