

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Effectiveness of Ivermectin in the Treatment of Coronavirus Infection in Patients admitted to Educational Hospitals of Mazandaran in 2020

#### Protocol summary

##### Study aim

Determining the effectiveness of Ivermectin in the treatment of Covid-19 infection in hospitalized patients in Mazandaran educational hospitals in 2020

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. Study patients are divided into two groups by simple randomization method with random number table. The control group will receive the standard treatment and the intervention group will receive a single dose of Ivermectin in addition to the standard treatment.

##### Settings and conduct

Patients with coronavirus hospitalized in Mazandaran educational hospitals are randomly divided into two groups of intervention and control. The present study is double-blind so that patients and the care provider will be unaware of how the intervention and control group is allocated.

##### Participants/Inclusion and exclusion criteria

Patients with suspected Covid-19 hospitalized over the age of 5 years and weight more than 15 kg will be included in the study if they are satisfied.

##### Intervention groups

In the intervention group, along with the standard drugs of the national protocol for the treatment of coronavirus infection, a single dose of Ivermectin 3 mg oral tablet with a dose of 0.2 mg/kg of Tadbir Kala Jam Company will be used according to the following : weight 15-24, 3 mg ; Weight 25-3, 6 mg; Weight 36-50, 9 mg; Weight 51-80, 12 mg and weight over 80, 0.2 mg/kg

##### Main outcome variables

Clinical symptoms including fever, chills, sore throat, cough, shortness of breath, decreased appetite, abdominal pain, dizziness, insomnia, itching, joint pain, joint swelling, headache, nausea, vomiting, diarrhea, malaise, conjunctivitis, tachycardia, wheezing, rhonchus, retraction, hypotension, rash, other symptoms, and respiratory rate and O2 saturation will be recorded in

first, second, third, fourth, fifth, sixth, seventh day.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111224008507N3**

Registration date: **2020-06-27, 1399/04/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-06-27, 1399/04/07**

Update count: **0**

##### Registration date

2020-06-27, 1399/04/07

##### 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

2020-05-21, 1399/03/01

##### Expected recruitment end date

2020-08-22, 1399/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Effectiveness of Ivermectin in the Treatment of Coronavirus Infection in Patients admitted to Educational Hospitals of Mazandaran in 2020

## Public title

Evaluation of the effect of Ivermectin in the treatment of coronavirus infection

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients hospitalized with suspected Covid-19 Informed consent for inclusion in study Age above 5 years Weight above 15 kg

### Exclusion criteria:

Liver and kidney disease Patients with acquired immunodeficiency Consumption of warfarin and ACEI family drugs (captopril, enalapril, etc.) Breastfeeding

## Age

From 5 years old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

Participants will be randomly assigned to two groups of intervention and control with 33 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. The evaluator nurse of data recording is from out of the study and questionnaires will be provided in the form of coding to him/her. So, the present study is double-blinded.

## Placebo

Not 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

2020-04-11, 1399/01/23

#### Ethics committee reference number

IR.MAZUMS.REC.1399.057

## 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 symptoms including fever, chills, sore throat, cough, shortness of breath, decreased appetite, abdominal pain, dizziness, insomnia, itching, joint pain, joint swelling, headache, nausea, vomiting, diarrhea, malaise, conjunctivitis, tachycardia, wheezing, rhonchus, retraction, hypotension, rash, other symptoms

#### Timepoint

The first, second, third, fourth, fifth, sixth, seventh day

#### Method of measurement

Observation and record in checklist

### 2

#### Description

Respiratory rate and O2 saturation

#### Timepoint

The first, second, third, fourth, fifth, sixth, seventh day

#### Method of measurement

Pulse Oximeter

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group: In the control group, only standard drugs of the national protocol are used.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: In the intervention group, along with the standard drugs of the national protocol, a single dose of 3 mg Ivermectin oral tablet with a dose of 0.2 mg/kg of Tadbir Kala Jam Company will be used according to the following table: weight 15-24, 3 mg; Weight 25-35, 6 mg; Weight 36-50, 9 mg; Weight 51-80, 12 mg and weight over 80, 0.2 mg/kg

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Teaching hospitals of Mazandaran

##### Full name of responsible person

Modammad Sadegh Rezai, MD

##### 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

47128-55689

#### Phone

+98 11 3334 2334

#### Email

msaidi@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

Mohammadsadegh Rezai

##### Position

Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Infectious diseases

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**Postal code**

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**Phone**

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**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**

Research Expert

**Latest degree**

Master

**Other areas of specialty/work**

Midwifery

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Bouali Hospital, Pasdaran Boulevard, Sari

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**Province**

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**Phone**

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**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**

Yes - There is 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 Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Part of the data is available

**When the data will become available and for how long**

Starting in January 2021

**To whom data/document is available**

All people

**Under which criteria data/document could be used**

Nothing

**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**