Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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)

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+98 11 3334 2334

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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
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Postal code
4815838477
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+98 11 3334 2334
Email
drmsrezaii@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
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Postal code
47128-55689
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+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
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Person responsible for scientific inquiries

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Mazandaran University of Medical Sciences
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Position
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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
Research Expert

Latest degree
Master

Other areas of specialty/work
Midwifery

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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
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: drmsrezaii@yahoo.com

What processes are involved for a request to access data/document
After contact, information is sent within a few days

Comments