

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Oct 2020

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

Mohammadsadegh Rezai

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1325 7230

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

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

Research Expert

Latest degree

Master

Other areas of specialty/work

Midwifery

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

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