

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Sep 2026

The effect of adding SOVODAK (sofosbuvir+daclatasvir) to the treatment protocol of COVID-19 outpatients: A Clinical Trial Study

Protocol summary

Study aim

Determining of adding SOVODAK (sofosbuvir + daclatasvir) to the treatment protocol of COVID-19 outpatients: A Clinical Trial Study

Design

A clinical trial study will have a control group with a parallel design

Settings and conduct

This study will be performed in Miandrood Medical Clinic. One group of single-drug therapies included hydroxychloroquine tablets (200 mg twice daily for 7 days), the other group of two-drug therapies included a combination of hydroxychloroquine (200 mg twice daily for 7 days) and sudak tablets (60/400 mg). Grams once a day) will receive. Treatment will be with azithromycin capsules (500 mg for 6 days) with naproxen tablets (500 mg, 2 times a day for 7 days) and pantoprazole tablets 40 mg for both groups. Patients in both groups will be given training such as adequate rest, quarantine principles, and breathing capacity training.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients with Quaid 19 confirmed by CT scan findings Exclusion criteria: Amiodarone use and patients with specific underlying diseases such as renal failure

Intervention groups

The intervention group will receive hydroxychloroquine + SOVODAK and the comparison group will receive hydroxychloroquine.

Main outcome variables

1- Symptoms ending 2- Lymphopenic condition 3- CRP status 4- SPO2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200403046926N1**

Registration date: **2020-04-11, 1399/01/23**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-11, 1399/01/23**

Update count: **0**

Registration date

2020-04-11, 1399/01/23

Registrant information

Name

Fatemeh Roozbeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 3310 8690

Email address

roozbeh@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-08, 1399/01/20

Expected recruitment end date

2020-05-19, 1399/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of adding SOVODAK (sofosbuvir+daclatasvir) to the treatment protocol of COVID-19 outpatients: A Clinical Trial Study

Public title

The effect of SOVODAK in the treatment of COVID-19

patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Diagnosis by CT scan with clinical symptoms
 Consent to attend the study
 Lymphocyte count less than 1100
 Positive CRP test
Exclusion criteria:
 History of kidney failure
 Pregnancy
 Amiodarone consumer

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be divided into two groups by Block Randomization. The block size is 4 people and a random list will be created by the sealed envelope site. To hide the drugs, they are placed in the required number in the envelope. Then, according to the random codes created, one or two envelopes will be placed in a larger envelope

Blinding (investigator's opinion)
Not blinded

Blinding description

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
 Miandrood Medical Center
City
 Sari
Province
 Mazandaran
Postal code
 ۴۸۱۵۷۳۳۹۷۱

Approval date
2020-04-01, 1399/01/13

Ethics committee reference number

IR.MAZUMS.REC.1399.017

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

B34.2

ICD-10 code description

Coronavirus infection, unspecified

Primary outcomes

1

Description

Symptoms ending

Timepoint

During the study

Method of measurement

Clinical examination

2

Description

Lymphopenic Status

Timepoint

Before the intervention and the seventh day

Method of measurement

Counting lymphocytes

3

Description

C-reactive protein Status

Timepoint

Before the intervention and the seventh day

Method of measurement

C-reactive protein serological test

4

Description

Saturation of Peripheral Oxygen

Timepoint

Before the intervention and the seventh day

Method of measurement

Pulseimetry

Secondary outcomes

1

Description

Need hospitalization

Timepoint

Depending on the situation

Method of measurement

Depending on the patient's condition

Intervention groups

1

Description

Intervention group: COVID-19 Patients receiving hydroxychloroquine + SOVODAK

Category

Treatment - Drugs

2

Description

Control group: COVID-19 Patients receiving hydroxychloroquine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Miandrood Medical Center

Full name of responsible person

Fatemeh Roozbeh

Street address

Miandrood, Surak, Imam Khomeini St., Ashouri Medical Clinic

City

Sari

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Mazandaran

Postal code

4815733971

Phone

+98 11 3388 4579

Email

roozbeh@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Professor Majid Saeedi

Street address

Vice-Chancellor for Research, Moallem Sq.

City

Sari

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Mazandaran

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4817844718

Phone

+98 11 3448 4800

Email

msaeedi@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

Fatemeh Roozbeh

Position

Non-faculty physician

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for scientific inquiries

Contact

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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 Roozbeh
Position
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Other areas of specialty/work
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Email
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

The SPSS data file can be published

When the data will become available and for how long

After publication

To whom data/document is available

Scholars

Under which criteria data/document could be used

Use for review studies

From where data/document is obtainable

Correspondence E-mail

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

Request via email

Comments