

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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****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

#### Province

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

#### Province

Mazandaran

#### Postal code

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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Mazandaran University of Medical Sciences

#### Full name of responsible person

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#### Position

Non-faculty physician

#### Latest degree

Specialist

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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**  
Non-faculty physician  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
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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