Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Nov 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 sealedenvelope 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
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Sari
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4815733971
Phone
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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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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
Street address
Miandrood, Surak, Imam Khomeini St., Ashouri Medical Clinic
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Person responsible for scientific inquiries

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Person responsible for updating data

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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