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
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**
- Not used

**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**
- ۱۷۹۳۳۷۵۱۸۴

**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

Province
Mazandaran

Postal code
481573971

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

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

City
Sari

Province
Mazandaran

Postal code
481573971

Phone
+98 11 3388 4579

Email
roozbeh@mazums.ac.ir

Person responsible for scientific 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
Medical Clinic
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3388 4579
Email
roozbeh@mazums.ac.ir

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
Infectious diseases
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

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