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 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**  
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  
1793375184  

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
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Mazandaran
Postal code
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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
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

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