Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of ANIF1 antiviral drug in COVID-19 patients: A Randomized Clinical Trial

Protocol summary

Study aim
Evaluation of clinical and laboratory effect of ANIF1 new antiviral drug in COVID-19 patients

Design
Clinical trial, double blind, with control group, randomized.patients and docters dont know about which group they are ,drug and placebo,.an accidental tabale number use to decrese the bias

Settings and conduct
Eligible patients are selected and introduced to the nurse to deliver the drug package,.afterrandomizatin The package includes one syrup in two types of antiviral drug with placebo tablets and another syrup of multivitamins and chloroquine. Blood samples and nasal swabs will be taken for testing.

Participants/Inclusion and exclusion criteria
Patients suspected of having coronavirus will enter the initial screening with the initial symptoms of fever, cough, shortness of breath, myalgia, weakness, or gastrointestinal symptoms. In case of lymphopenia less than 1100, patients will be sent for RT-PCR test to confirm the disease, as well as patients in the CT scan of the lungs who have been diagnosed with a definite case of coronavirus and are between 18 and 65 years old will entered to the study. Also patients 1- Fever above 38 degrees 2- Lymphocytes count less than 101 3- Positive CRP 4- Positive respiratory symptoms (cough or shortness of breath or tachypnea or ...) 5- Symptoms of pulmonary involvement in lung or CT scan will enter the study will be entered to the study we exclude end organ disease and severe imunnocompromised patients

Intervention groups
In 30 subjects, the ANIF1-tested group will receive 10 cc of oral syrup three twice a day for7days at specific doses. The control group will be 30 patients who will receive the standard medication regimen as recommended by the national standard protocol.(HCQ200BID and/or kaletra400mg bid)+ SYRUP MULTIVITAMIN as placebo

Main outcome variables
RT-PCR and CT scan of the lungs, level of inflammatory biomarkers

General information

Reason for update

Acronym
ANIF1

IRCT registration information
IRCT registration number: **IRCT20190727044343N3**
Registration date: **2020-06-12, 1399/03/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-12, 1399/03/23**
Update count: **0**

Registration date
2020-06-12, 1399/03/23

Registrant information

Name
Lotfollah Davoodi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 4221 8231

Email address
lotfdavoodi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-09, 1399/03/20

Expected recruitment end date
2020-06-20, 1399/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of ANIF1 antiviral drug in COVID-19 patients: A Randomized Clinical Trial

Public title
ANIF1 effect on COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
COVID-19 diagnosis based on Lung Ct-Scan COVID-19 diagnosis based on RT-PCR Lymphopenia less than 1100 fever more than 38 degrees Positive CRP Positive respiratory symptoms Gastroitestinal symptms
Exclusion criteria:
intubated patients with severe respiratory disease patients with severe co-morbidity and end stage disease Oral intolerance onset of symptoms more than 10 days pregnant women severe Immuncompromised patients
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
patients will be assigned one in between and randomly into two groups with accidental code
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients will receive same taste and smell syrups, one with ANIF1 and other with multivitamin and chloroquine. Eligible patients are selected and introduced to the nurse to deliver the drug package, and the nurse gives one of the packages, respectively. The package includes one syrup in two. It is an antiviral drug with placebo tablets and another multivitamin and chloroquine syrup. Patients and researchers are unaware of the contents of the package.
Placebo
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
Moallem
City
Sari
Province
Mazandaran
Postal code
4817844718
Approval date
2020-04-11, 1399/01/23
Ethics committee reference number
IR.MAZUMS.REC.1399.067

Health conditions studied

1

Description of health condition studied
COVID-19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
RT-PCR test.IL-6,CRP
Timepoint
at the beginning and end of study
Method of measurement
nasopharyngeal swab

2

Description
lung CT-Scan
Timepoint
at the beginning and end of study
Method of measurement
CT-Scan

Secondary outcomes

1

Description
inflammatory biomarkers IL6,CRP

Timepoint
at the beginning and end of study
Method of measurement
blood test

Intervention groups

1

Description
Intervention group: ANIF1 with specific doses of 10 cc as an oral syrup, 2 times a day for 7 days
Category
Treatment - Drugs

2

Description
Control group: standard medication regimen according to the national standard protocolAND multivitamin syrup as placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Coronavirus center
Full name of responsible person
Lotfollah Davoodi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sceinces
Full name of responsible person
Majid Saeedi
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Vice Chancellery for Research and Technology of Mazandaran University of Medical Sciences, Moallem Square
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
kimia cell pajoohan
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Lotfollah Davoodi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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

Clinical Study Report
Yes - There is a plan to make this available

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

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

Title and more details about the data/document
Data will be Released after the article is published

When the data will become available and for how long
after study conduction

To whom data/document is available
health care workers

Under which criteria data/document could be used
for further investigation and therapeutic uses

From where data/document is obtainable
Person in charge for study

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

Comments