

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 doctors don't know about which group they are, drug and placebo, an accidental tabale number use to decrease the bias

Settings and conduct

Eligible patients are selected and introduced to the nurse to deliver the drug package, after randomization. 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 enter 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 immunocompromised patients

Intervention groups

In 30 subjects, the ANIF1-tested group will receive 10 cc of oral syrup three times a day for 7 days at specific doses. The control group will be 30 patients who will receive the standard medication regimen as recommended by the national standard protocol. (HCQ200 BID and/or kaletra 400mg 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
Gastrointestinal symptoms

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 Immunocompromised 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

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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 protocol AND multivitamin syrup as placebo

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Coronavirus center

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saedi

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Vice Chancellery for Research and Technology of
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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 pajooan

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

Infectious diseases

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Person responsible for updating data

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Name of organization / entity

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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