

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effect of febuxostat against lung injury induced by COVID-19 virus in infected patients: A clinical trial study

Protocol summary

Study aim

The effect of febuxostat on pulmonary complications of COVID-19

Design

This is a double-blind, parallel-controlled clinical trial that will be conducted in two groups of 30 patients referred to coronavirus center.

Settings and conduct

Patients with COVID-19, referred to the coronavirus center of Sari, will receive one intervention if they do not need hospitalization in a double-blind, 30-person group.

Participants/Inclusion and exclusion criteria

This study will be conducted on patients with coronavirus 2019, and critically ill patients who need hospitalization will not be included.

Intervention groups

Intervention group will receive acetaminophen + febuxostat and comparison group will receive acetaminophen + hydroxychloroquine.

Main outcome variables

Fever; Lymphocyte count; CRP; CT scan findings

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190727044343N1**

Registration date: **2020-04-05, 1399/01/17**

Registration timing: **retrospective**

Last update: **2020-04-05, 1399/01/17**

Update count: **0**

Registration date

2020-04-05, 1399/01/17

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

2020-03-16, 1398/12/26

Expected recruitment end date

2020-04-02, 1399/01/14

Actual recruitment start date

2020-03-15, 1398/12/25

Actual recruitment end date

2020-03-27, 1399/01/08

Trial completion date

2020-04-09, 1399/01/21

Scientific title

The effect of febuxostat against lung injury induced by COVID-19 virus in infected patients: A clinical trial study

Public title

Effect of febuxostat against coronavirus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients infected with COVID-19

Exclusion criteria:

Severe disease patients that need hospitalization.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with sealed envelope

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient receives the medication (intervention or comparison) in sealed envelopes that are coded. The coding is done by a project colleague and the physician, assessor and patient are blind.

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

Moallem

City

Sari

Province

Mazandaran

Postal code

4817844718

Approval date

2020-03-10, 1398/12/20

Ethics committee reference number

IR.MAZUMS.REC.1398.1452

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

CT-scan findings

Timepoint

Before the intervention and 2 weeks after the intervention

Method of measurement

CT-scan

Secondary outcomes

1

Description

Fever

Timepoint

Before the intervention and 5 days after the intervention

Method of measurement

Thermometer

2

Description

Lymphocyte count

Timepoint

Before the intervention and 5 days after the intervention

Method of measurement

CBC test

3

Description

CRP

Timepoint

Before the intervention and 5 days after the intervention

Method of measurement

Laboratory

Intervention groups

1

Description

Intervention group: Acetaminophen + Febuxostat

Category

Treatment - Drugs

2

Description

Control group: Acetaminophen + Hydroxychloroquine

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Coronavirus center

Full name of responsible person

Lotfollah Davoodi

Street address

Amirmazandarani

City

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Province

Mazandaran

Postal code

4816633131

Phone

+98 11 3336 1700

Fax**Email**

lotfdavoodi@yahoo.com

Mazandaran University of Medical Sciences

Full name of responsible person

Lotfollah Davoodi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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

Mazandaran University of Medical Sciences

Full name of responsible person

Majid Saeedi

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Mazandaran

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4817844718

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Email

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

Mazandaran University of Medical Sciences

Full name of responsible person

Lotfollah Davoodi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Person responsible for updating data**Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Lotfollah Davoodi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is 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

SPSS data file can be shared

When the data will become available and for how long

Post Publication

To whom data/document is available

The data will be available to researchers

Under which criteria data/document could be used

Can be used in secondary studies

From where data/document is obtainable

Mail to lotfdavoodi@yahoo.com

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

Will be sent after receiving the email

Comments