

# 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**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4816633131  
**Phone**  
+98 11 3336 1700  
**Fax**  
**Email**  
lotfdavoodi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Mazandaran University of Medical Sciences  
**Full name of responsible person**  
Majid Saeedi  
**Street address**  
Moallem  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4817844718  
**Phone**  
+98 11 3325 7230  
**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**

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  
**Street address**  
Amirmazandarani  
**City**  
Sari  
**Province**  
Mazandaran  
**Postal code**  
4816633131  
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+98 11 3336 1700  
**Email**  
lotfdavoodi@yahoo.com

## 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**  
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**Email**  
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## Person responsible for updating data

#### Contact

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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**