Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)
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+98 11 4221 8231
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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
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Amirmazandarani
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4816633131
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lotfdavoodi@yahoo.com

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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4817844718
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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 Sceinces
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
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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
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