# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## Effects of pentoxifyliine on clinical outcomes of patients with COVID19: A randomaized double-blind clinical trial

### Protocol summary

**Study aim**

Determining the effectiveness of pentoxifylline in improving the clinical symptoms of patients with Quid 19 compared with placebo

**Design**

This study is a randomized, double-blind clinical trial with a control group and a sample size of 60 people.

**Settings and conduct**

All patients referred to Bu Ali Sina Educational-Medical Center who are eligible according to the inclusion criteria will be randomly candidate to receive pentoxifylline or placebo for 5 days. The patients and prescriber will not be aware of intervention type. Demographic characteristics, clinical outcomes and laboratory test changes will be recorded and analyzed.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria are adults over the age of 18 with a diagnosis of COVID-19 clinical criteria (presence of any symptoms of cough, shortness of breath, fever, and CT scan of the lung for evidence of COVID-19 infection) or PCR . Allergy to pentoxifylline , pregnancy, lactation, renal and hepatic failure, a history of cerebral or ocular bleeding, a history of pentoxifylline use, onset of symptoms for more than 14 days, and glomerular infiltration less than 30 ml / min will be excluded.

**Intervention groups**

For all patients, the 400 mg hydroxychloroquine diet regimen is given as a stat dose and lopinavir / ritonavir every 12 hours and interferon beta 1b 8 million units daily as subcutaneous injection. Patients are randomized for receiving pentoxifylline or placebo based on a random schedule. Pentoxifylline will be given in 400 mg tablets three times a day for at least 5 days, and the control group will receive the same amount of placebo tablets.

**Main outcome variables**

•The serum levels of inflammatory biomarkers • Oxidative stress indices determination • Determination of mortality reduction • Determination of the reduction in patients' need for intensive care and invasive oxygenation procedures

### General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20190804044429N4**
Registration date: **2020-11-25, 1399/09/05**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-25, 1399/09/05**
Update count: **0**

**Registration date**

2020-11-25, 1399/09/05

**Registrant information**

**Name**

Monireh Ghazaeian

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 8863 6864

**Email address**

ghazaeianm@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-11-10, 1399/08/20

**Expected recruitment end date**

2020-12-20, 1399/09/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**
empty

**Scientific title**
Effects of pentoxifyliine on clinical outcomes of patients with COVID19: A randomaized double-blind clinical trial

**Public title**
pentoxifyliine in COVID-19

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Inclusion criteria are adults over the age of 18 with a diagnosis of COVID-19 based on clinical criteria (presence of any symptoms of cough, shortness of breath, fever, and CT scan of the lung for evidence of involvement consistent with COVID-19 infection) or PCR.

**Exclusion criteria:**
History of allergy to any drugs of therapeutic regimen pregnancy and lactation renal and hepatic disease History of cerebral or ocular bleeding Glomerular infiltration less than 30 ml / min History of use of pentoxifylline Symptoms start more than 14 days before

**Age**
From **18 years** old

**Gender**
Both

**Phase**
2-3

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **2**
Blood cell count, sodium, potassium, INR, PT, urea and creatinine daily, biochemical tests including liver enzymes, electrolytes including calcium, phosphorus, magnesium and albumin twice a week and CRP and lactate dehydrogenase are checked every other day. Serum samples are taken from all patients on the first day and on the fifth day of the study to measure the serum level of interleukin 6 and factors related to cellular oxidation pathways.

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Patients are randomized for receiving pentoxifylline or placebo based on a random table. Drugs and placebo will be provided to patients in pre-prepared packages based on random numbers and in accordance with the random table.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
This study is double blind. Outcome elevator and participant are blinded (double blind) and aware from grouping (intervention or placebo).

**Placebo**
Used

**Assignment**
Parallel

**Other design features**
Control group in this study is defined as patients who admitted in hospital and received national therapeutic regimen for COVID-19 before the approval of the study proposal compatible with inclusion criteria.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Mazandaran University of Medical Sciences

**Street address**
Ibn Sina Hospital, Pasdaran Blvd

**City**
Sari

**Province**
Mazandaran

**Postal code**
4816864193

**Approval date**
2020-11-10, 1399/08/20

**Ethics committee reference number**
IR.MAZUMS.REC.1399.744

## Health conditions studied

### 1

**Description of health condition studied**
COVID-19 pneumonia

**ICD-10 code**
U07.1

**ICD-10 code description**
COVID-19, virus identified

## Primary outcomes

### 1

**Description**
Clinical response to therapeutic regimen by respiratory rate

**Timepoint**
Before intervention and daily during the study

**Method of measurement**
physical exam

### 2

**Description**
Clinical response to therapeutic regimen by blood oxygen saturation

**Timepoint**
Before intervention and daily during the study
**Method of measurement**
pulse oximeter

**3**

**Description**
Clinical response to therapeutic regimen by fever recovery
**Timepoint**
Before intervention and daily during the study
**Method of measurement**
thermometer

**4**

**Description**
therapeutic regimen safety
**Timepoint**
Daily during the study
**Method of measurement**
patient tolerability

**5**

**Description**
Clinical response to therapeutic regimen by LDH level reduction
**Timepoint**
before intervention and then three times weekly during the study
**Method of measurement**
LDH laboratory kite

**6**

**Description**
Clinical response to therapeutic regimen by CRP level reduction
**Timepoint**
before intervention and then three times weekly during the study
**Method of measurement**
CRP laboratory kite

**7**

**Description**
Clinical response to therapeutic regimen by lymphocyte count recovery
**Timepoint**
before intervention and then daily during the study
**Method of measurement**
Cell blood count test

## Secondary outcomes

**1**

**Description**
Hospital stay duration
**Timepoint**
End of treatment
**Method of measurement**
Patient file

**2**

**Description**
Mortality rate
**Timepoint**
Daily during the study
**Method of measurement**
patient file

**3**

**Description**
IL-6 concentration
**Timepoint**
The first and fifth day of hospitalization
**Method of measurement**
ELISA kit

**4**

**Description**
Total antioxidant level
**Timepoint**
The first and fifth day of hospitalization
**Method of measurement**
Spectroscopy

**5**

**Description**
Carbonyl protein
**Timepoint**
The first and fifth day of hospitalization
**Method of measurement**
Spectroscopy

**6**

**Description**
Lipid peroxidation rate
**Timepoint**
The first and fifth day of hospitalization
**Method of measurement**
Spectroscopy

**7**

**Description**
Glutathione concentration
**Timepoint**
The first and fifth day of hospitalization
**Method of measurement**
Spectroscopy

## Intervention groups

**1**

**Description**

Intervention group: therapeutic regime including hydroxychloroquine 400 mg stat and lopinavir/ritonavir and250 mcg interferon beta 1 b subcutaneous injection every other day for at least 3 doses with pentoxyfylline tablet of Arya company at dose of 400 mg every 8 hours for 5 days

**Category**

Treatment - Drugs

**2**

**Description**

Control group: Patients with inclusion criteria who received therapeutic regimen of hydroxychloroquine 400 mg stat and lopinavir/ritonavir and250 mcg interferon beta 1 b subcutaneous injection every other day for at least 3 doses for 5 days.

**Category**

Placebo

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Ibn Sina Hospital

**Full name of responsible person**

Monireh Ghazaeian

**Street address**

Ibn Sina hospital, Pasdaran Blvd, Sari, Mazandaran province

**City**

sari

**Province**

Mazandaran

**Postal code**

4815733971

**Phone**

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**Email**

ghazaeianm@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Majid Saeedi

**Street address**

Vice Chancellor for Research, Mazandaran University of Medical Sciences, Joybar 3way

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Sari

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**Postal code**

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**Phone**

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majsaeedi@gmail.com

**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**

منیره غزائیان

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Ibn Sina hospital, Pasdaran Blvd, Sari, Mazandaran province, Iran.

**City**

sari

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**Postal code**

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Monireh Ghazaeian

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

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Monireh Ghazaeian

**Position**
Assistant professor

**Latest degree**
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**Other areas of specialty/work**
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**Email**
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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**
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**
Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**
Not applicable

**Data Dictionary**
Not applicable

**Title and more details about the data/document**
The results of trial including analysis data and method of the study

**When the data will become available and for how long**
At the time of publication, the data of the study will be available.

**To whom data/document is available**
academic researchers, medical team and scientific institutes

**Under which criteria data/document could be used**
For research and practical purposes

**From where data/document is obtainable**
Dr. Monireh Ghazaeian, Faculty of pharmacy, Mazandaran University of Medical Sciences.

**What processes are involved for a request to access data/document**
The scientific responsible person of the study will reply to the request within 10 days. ghazaeianm@gmail.com

**Comments**