Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 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

+98 11 3334 3011

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

City

Sari

Province

Mazandaran

Postal code

4816864193

Phone

+98 11 3448 4800

Email

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

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3334 3011

Email

ghazaeianm@gmail.com

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

Medical Pharmacy

Street address
Ibn Sina hospital, Pasdaran Blvd

City
Sari

Province
Mazandaran

Postal code
48157-33971

Phone
+98 11 3334 3010

Email
ghazaeianm@gmail.com

Person responsible for updating data

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
Medical Pharmacy

Street address
Ibn Sina hospital, Pasdaran Blvd

City
Sari

Province
Mazandaran

Postal code
4815733971

Phone
+98 11 3334 3010

Email
ghazaeianm@gmail.com

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