

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of the efficacy and safety of oral pentoxifylline in treatment and recovery of patients with COVID-19 admitted in Rasoul Akram and firoozgar hospitals treated with routine protocols, A randomized controlled clinical trial

Protocol summary

Study aim

Evaluation of the efficacy and safety of oral pentoxifylline in treatment and recovery of patients with COVID-19 admitted in Rasoul Akram and firoozgar hospitals who are under treatment with routine protocols, A randomized controlled clinical trial

Design

Randomization will only be done at the center level, which will be done in a simple random way (coin toss). Then all patients in the selected center will receive standard treatment in addition to pentoxifylline treatment in control group in another center. In this plan, patients and evaluators are not blind.

Settings and conduct

Hazrat Rasool akram and Firoozgar hospitals, covid-19 admission wards for conduct a randomized clinical trial

Participants/Inclusion and exclusion criteria

Inclusion and exclusion criteria: aged 18-90 years, moderate to severe admitted stable COVID patients, not any bleeding disorders, no heart attack and stroke, no ocular and cerebral hemorrhage, not pregnant or breastfeeding, intolerance or allergy to PTX or xanthines, no gastric ulcer, no porphyria, no significant impairment of kidney or liver or heart function, no history of major surgery (last 2 weeks), no cancer, no use of any therapeutic blood thinners, pressure drop below (10) or unstable vital signs

Intervention groups

Treatment in both control and intervention groups will be based on the use of common treatment protocols in patients with covid-19. In the intervention group, oral PTX (400 milligram TDS for up to 2 weeks) will be added to the routine treatment (hydroxychloroquine (400 milligram stat then 200 milligram BID)+sofosbuvir/daclatasvir (400/60 milligram)), for 7-10 days.

Main outcome variables

fever/cough/dyspnea/o2 level/duration of administration/laboratory parameters/radiologic changes/ICU admission/death

General information

Reason for update

Changing the final sample size at the end of the study from 86 to 150 patients

Acronym

IRCT registration information

IRCT registration number: **IRCT20170809035597N2**

Registration date: **2020-11-16, 1399/08/26**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-14, 1400/11/25**

Update count: **2**

Registration date

2020-11-16, 1399/08/26

Registrant information

Name

Azadeh Goodarzi

Name of organization / entity

Iran University of Medical Sciences (IUMS), Rasool Akram hospital, Department of Dermatology

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-17, 1399/05/27

Expected recruitment end date

2020-11-17, 1399/08/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and safety of oral pentoxifylline in treatment and recovery of patients with COVID-19 admitted in Rasoul Akram and firoozgar hospitals treated with routine protocols, A randomized controlled clinical trial

Public title

Efficacy and safety of pentoxifylline in treatment and recovery of patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Admitted patients with COVID-19 Moderate to severe disease Stable patients Patients should not have bleeding disorders Patients do not have a history of heart attack and stroke Patients without history of ocular or cerebral hemorrhage No pregnancy or breastfeeding Patients without history of intolerance to PTX or other xanthines such as caffeine, theophylline and tobromine Patients without gastric ulcers Patient without history of porphyria Patients with no prominent renal or hepatic or cardiac dysfunction Patients without history of major surgery in the past 2 weeks Patients without history of cancer Patients without need to use any therapeutic blood thinners, including aspirin and warfarin

Exclusion criteria:

Allergy to any of the drugs studied, including pentoxifylline Occurrence of any bleeding during the study (in the stomach, brain, eyes, ...) Drug intolerance or the occurrence of any severe side effects during treatment, such as gastrointestinal intolerance, does not respond to pre-determined measures of anti-acids... or the occurrence of skin drug reactions to the received treatment protocol and ... Being pregnant during the study Occurrence of heart attack and stroke during the study Drop in pressure below 10 mm Hg or instability of the patient's vital signs Require intubation during study or hospitalization in the ICU Increase in the severity of COVID-19 disease during the study so that the need for hospitalization in the ICU or the need to change the treatment protocol The use of a therapeutic drug other than the standard drug in this study

AgeFrom **18 years** old to **90 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **150****Randomization (investigator's opinion)**

Randomized

Randomization description

Randomization will only be done at the center level, which will be done in a simple random way (coin toss). Since the samples required for the study will be collected from two centers, so one center will be the center of the intervention randomly and one center will be the center of control randomly and in each center the basic treatment regimen will be prescribed on a regular basis (HydroxyChloroquine + Sofosbuvir) and the intervention center will receive pentoxifylline in addition to the mentioned diet, so the blinding of patients is not seen in the plan, and on the other hand each center will have its own special and trained evaluator, and therefore there is no blinding of evaluator and only the data analyst who does not know the type of drug used in the centers is blind.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Iran University of medical sciences

Street address

Nyayesh Street, Sattarkhan Avenue, Rasoul Akram Hospital, Tehran, Iran

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1445613131

Approval date

2020-08-25, 1399/06/04

Ethics committee reference number

IR.IUMS.REC.1399.458

Health conditions studied**1****Description of health condition studied**

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Time to improve symptoms such as cough, shortness of breath and lethargy

Timepoint

At the beginning of the hospitalization/ two weeks after treatment

Method of measurement

Clinical evaluation

2

Description

O2 saturation

Timepoint

At the beginning of the hospitalization/ two weeks after treatment

Method of measurement

Clinical evaluation and pulse oximetry

3

Description

Re-hospitalization after discharge

Timepoint

At the beginning of the hospitalization/ two weeks after treatment

Method of measurement

Clinical evaluation

4

Description

Duration of hospitalization

Timepoint

After discharge

Method of measurement

Days

5

Description

Evaluation of laboratory parameters as a series of factors: PCR and LDH, CBC, ESR, CRP

Timepoint

At the beginning of the hospitalization/ during hospitalization/ at discharge time

Method of measurement

Lab data analysis

6

Description

Check for changes in anti-inflammatory parameters (TNF-ALPHA and IL-6 if measuring kits are available)

Timepoint

At the beginning of the hospitalization/ at discharge time

Method of measurement

Lab data analysis

7

Description

Investigation of radiological changes at the beginning of hospitalization and during hospitalization if possible

Timepoint

At the beginning of the hospitalization/ during hospitalization

Method of measurement

Radiographic changes

8

Description

Need to ICU admission

Timepoint

During hospitalization

Method of measurement

Clinical evaluation

9

Description

Recovery or death

Timepoint

During hospitalization or in follow-up period

Method of measurement

Observation

Secondary outcomes

1

Description

Side effects

Timepoint

Time to start the intervention/ during hospitalization, two weeks after interventions

Method of measurement

Clinical, laboratory evaluation

2

Description

Need change initial treatment or add new drug to the regimen

Timepoint

During hospitalization

Method of measurement

Clinical assessment

Intervention groups

1

Description

Intervention group: In the intervention group, oral PTX (400 milligram TDS for up to 2 weeks) will be added to

the routine treatment (hydroxychloroquine (400 milligram stat then 200 milligram BID)+sofosbuvir/daclatasvir (400/60 milligram)), for 7-10 days.

Category

Treatment - Drugs

2

Description

Control group: In the control group, routine treatment as (hydroxychloroquine (400 milligram stat then 200 milligram BID)+sofosbuvir/daclatasvir (400/60 milligram)), for 7-10 days, will be administered.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital

Full name of responsible person

Azadeh Goodarzi

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2

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Azadeh Goodarzi, Simin Almasi

Street address

Valadi Street, Valiasr Sq., Firoozgar Hospital, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Rasoul Akram Hospital Clinical research development Center (RCRDC)

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iranshahr University of Medical Sciences

Full name of responsible person

Azadeh Goodarzi

Position

Assistant Professor of Dermatology

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Full name of responsible person
Azadeh Goodarzi
Position
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Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Title and more details about the data/document

Evaluation of the efficacy and safety of oral pentoxifylline in treatment and recovery of patients with COVID-19 admitted in Rasoul Akram and firoozgar Hospitals who are under treatment with routine protocols, A randomized controlled clinical trial

When the data will become available and for how long

The data will be available after 6-7 month starting the study

To whom data/document is available

For all people and physician may have concern about COVID-19 and its management

Under which criteria data/document could be used

In patients with COVID-19 as a probable adjuvant therapy in the setting of no contraindication for this drug

From where data/document is obtainable

Via related published article

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

Purchase published article

Comments