Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 (hydroxychlroquine (400 milligram stat then 200 miligram BID)+sofosbuvir/daclatasvir (400/60 milligram)), for 7-10 days.

Main outcome variables
fever/cough/dyspenia/o2 level/duration of administration/laboratory parameters/ radiologicchanges/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)

Phone
+98 66502040

Email address
goodarzi.a@iums.ac.ir

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
Age
From **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 scinces
Street address
Nyayesh Street, Sattarkhan Avenue, Rasoul Akram Hospital, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
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 oximetery

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 (hydroxychlroquine (400 milligram stat then 200 miligram BID)+sofosbuvir/daclatasvir (400/60 milligram)), for 7-10 days.

Category

Treatment - Drugs

2

Description

Control group: In the control group, routine treatment as (hydroxychlroquine (400 milligram stat then 200 miligram 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

Street address

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

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6650 2040

Email

azadeh_goodarzi1984@yahoo.com

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

City

Tehran

Province

Tehran

Postal code

4871115937

Phone

+98 21 6650 2040

Email

azadeh_goodarzi1984@yahoo.com

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)

Street address

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

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6650 2040

Email

azadeh_goodarzi1984@yahoo.com

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

Street address

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

City

Tehran

Province

Tehran

Postal code
1445613131
Phone
009866502040
Email
azadeh_goodarzi1984@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran 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
Street address
Nyayesh Street, Sattarkhan Avenue, Rasoul Akram Hospital, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6650 2040
Email
azadeh_goodarzi1984@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Iran 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
Street address
Nyayesh Street, Sattarkhan Avenue, Rasoul Akram Hospital, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
009866502040
Email
azadeh_goodarzi1984@yahoo.com

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
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