Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the effect of Pentoxifylline drug on the clinical progression of covid-19 in patients with acute respiratory failure of moderate severity in the intervention and control groups

Protocol summary

Study aim

Pentoxifylline is effective in reducing the symptoms of respiratory distress in patients with moderate severity and improving oxygen saturation and can be used as an effective drug in Coevid 19.

Design

Data are collected in two groups of intervention and control and will be analyzed by SPSS software. Clinical trial with control group, with parallel group and single-phase phase 2 blind on 70 patients.

Settings and conduct

The study will be performed interventionally and after obtaining informed consent from patients and pentoxifylline will be given to the intervention group at a dose of 400 mg once a day. Patients who refer to Ayatollah Taleghani Medical Training Center due to positive Covid will participate in the study. To blind a colleague, another doctor will be in charge of assigning patients. The statistician will also be unaware of the intervention and control group and will conduct the study in two groups A and B.

Participants/Inclusion and exclusion criteria

Patients over 18 years of age whose test results are positive and have a lung T-scan course and their blood oxygen saturation with canola nasal and simple mask is 90% and higher.

Intervention groups

34 patients in each group who wish to participate in the study, 34 patients are in the control group. Matching will be done in terms of receiving RamedSavier and Corton.

Main outcome variables

If pentoxifylline is effective in reducing the symptoms of respiratory distress in patients with moderate severity and improving oxygen saturation, it can be used as an effective drug in covid 19.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210517051326N1**
Registration date: **2023-04-27, 1402/02/07**
Registration timing: **retrospective**

Last update: **2023-04-27, 1402/02/07**
Update count: **0**

Registration date

2023-04-27, 1402/02/07

Registrant information

Name

Sedighe sadat Akhlaghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2303 1799

Email address

sediqakhlaghi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Investigating the effect of Pentoxifylline drug on the clinical progression of covid-19 in patients with acute respiratory failure of moderate severity in the intervention and control groups

Public title
Effect of pentoxifillyn on COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Positive test of PCR test COVID-19 Age more than 18 SpO2 more than 90%

Exclusion criteria:
Sever COVID-19 Need for treatment with Mechanical ventilation Need for treatment with high dose corticosteroids Nausea and vomiting and GIB

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
White and black color cards are used. 35 white cards and 35 black cards are prepared and randomly selected and placed in sealed envelopes from 1 to 70, respectively, and with the arrival of each patient, a special envelope is opened based on the card inside the patient in group A. (White card) or group B (black). The similarity of the two groups in terms of age, sex, underlying disease and drugs received (patients with moderate lung involvement, symptomatic therapy with painkillers (acetaminophen), antihistamines (diphenhydramine), vitamins C and D) will be statistically evaluated. .

Blinding (investigator's opinion)
Single blinded

Blinding description
To blind a colleague, another doctor will be in charge of assigning patients. The statistician will also be unaware of the intervention and control group and will conduct the study in two groups A a

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Organizational Committee of Ethics in Biomedical Research

Street address
Ayatollah Taleghani Hospital, Shahid Arabi St, Yemen St. Shahid Chamran Highway, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1985717413

Approval date
2022-05-19, 1401/02/29

Ethics committee reference number
IR.SBMU.RETECH.REC.1401.026

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
J96.01

ICD-10 code description
Acute respiratory failure with hypoxia

Primary outcomes

1

Description
Spo2

Timepoint
1st, 7th, 28th, 35th day

Method of measurement
Pulseoximetry

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A Participants with usual treatment (curcudone 35 mg daily, vitamin C loan 500 mg daily, heparin 5000 units every 12 hours, dexamethasone 4 mg IV daily), pentoxifylline 400 mg daily every 12 hours they receive.

Category
Treatment - Drugs

2

Description
Control group: Participants in this group receive the usual treatment (curcudone 35 mg daily, vitamin C loan 500 mg daily, heparin 5000 units every 12 hours, dexamethasone 4 mg IV daily).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
taleghani hospital
Full name of responsible person
Sedighe sadat Akhlaghi
Street address
Taleghani Hospital,Shahid Arabi St. Yemen St. Shahid Chamran Highway, Tehran
City
Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 2303 1335
Fax
+98 21 2243 2581
Email
sediqakhlaghi@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sedighe Sadat Akhlaghi
Street address
Assistant Professor of Education, Ayatollah Taleghani Hospital, first floor, next to the hemodialysis department of Taleghani Hospital, Arab Street, Yemen Street, Shahid Chamran Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 2303 1335
Fax
+98 21 2243 2581
Email
sediqakhlaghi@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sedeqe Sadat Akhlaghi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Assistant Professor of Education, Ayatollah Taleghani Hospital, First floor, Next to the Hemodialysis Department of Taleghani Hospital, Arab Street, Yemen Street, Shahid Chamran Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 2303 1335
Fax
+98 21 2243 2581
Email
sediqakhlaghi@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sedighe Sadat Akhlaghi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work

Internal Medicine

Street address

Assistant Professor of Education, Ayatollah Taleghani Hospital, First floor, next to the Hemodialysis Department of Taleghani Hospital, Arab Street, Yemen Street, Shahid Chamran Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717413

Phone

+98 21 2303 1335

Fax

+98 21 2243 2581

Email

sediqakhlaghi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Sedighe Sadat Akhlaghi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Assistant Professor of Education, Ayatollah Taleghani Hospital, First floor, Next to the Hemodialysis Department of Taleghani Hospital, Arab Street, Yemen Street, Shahid Chamran Highway, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985717413

Phone

+98 21 2303 1335

Fax

+98 21 2243 2581

Email

sediqakhlaghi@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

Others researchers can access via the co responder email

When the data will become available and for how long

6 months afters publish article of research

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

More research

From where data/document is obtainable

Others researchers can access via the co responder email

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

Others researchers can access via the co responder email

Comments