

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 Covid 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 pentoxifyllin 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

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Person responsible for scientific inquiries

Contact

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Shahid Beheshti University of Medical Sciences

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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

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