Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Feb 2026

The effect of pentoxifylline on hypoxia in non-intubated covid-19 patients hospitalized in the intensive care unit - randomized controlled clinical trial

Protocol summary

Study aim

The effect of pentoxifylline on hypoxia in non-intubated covid-19 patients hospitalized in the intensive care unit - randomized controlled clinical trial

Design

Clinical trial with intervention and control group, double-blind, randomized,parallel, phase 3 is performed on 100 patients

Settings and conduct

This study is performed on patients Covid 19 admitted to the intensive care unit of Vali-e-Asr Hospital in Birjand. after explaining the objectives of the study in the eligible group and obtaining patient satisfaction, patients is divided into two groups of intervention and control. It is randomly divided and the intervention is performed based on the study group. The study is blind for the patient and the intervening and analyzing person.

Participants/Inclusion and exclusion criteria

Admission requirements: confirmation of Covid-19 diagnosis by PCR test informed consent to participate in the study No history of allergy to methylxanthines Being hospitalized in the intensive care unit The patient should not be intubated arterial oxygen saturation less than 85% without oxygen therapy(room air or ambient air) Don t admission requirements: pregnancy and lactation Severe liver failure Severe renal failure Bleeding disorder and coagulopathy Hypersensitivity to the pentoxifylline(After prescribing)

Intervention groups

Both study groups will receive standard treatment. The intervention group will receive 400 mg oral pentoxifylline tablets made in Iran, Farabi Pharmaceutical Company with generic code 00970, three times a day (every 8 hours) for 72 hours, and the control group will receive placebo. The placebo prepared by Farabi Pharmaceutical Company will be taken orally three times a day (every 8 hours) for 72 hours.

Main outcome variables

Atrial Oxygen saturation, Measure of Arterial blood oxygen ,Blood Pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210623051677N1**
Registration date: **2021-08-27, 1400/06/05**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-27, 1400/06/05**
Update count: **0**

Registration date

2021-08-27, 1400/06/05

Registrant information

Name

rajab arbabpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3240 6421

Email address

rajab.arbabpor@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-25, 1400/06/03

Expected recruitment end date

2021-10-25, 1400/08/03

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of pentoxifylline on hypoxia in non-intubated covid-19 patients hospitalized in the intensive care unit - randomized controlled clinical trial

Public title
effect of pentoxifylline in COVID-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
confirmation of Covid-19 diagnosis by PCR test informed consent to participate in the study No history of allergy to methylxanthines Being hospitalized in the intensive care unit The patient should not be intubated arterial oxygen saturation less than 85% without oxygen therapy(room air or ambient air)
Exclusion criteria:
pregnancy and lactation Severe liver failure Severe renal failure Bleeding disorder and coagulopathy Hypersensitivity to the pentoxifylline(After prescribing)
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the randomized block method is used as four blocks with equal proportions of groups. The different permutations of the blocks (AABB, BABA, BBAA, ABBA, ABAB, and BAAB) will be numbered from one to six and then the random selection of blocks will be done using dice.
Blinding (investigator's opinion)
Double blinded
Blinding description
For blinding, drug and placebo are exactly the same in terms of color, taste and packaging, and concealment by inserting a special row number / code in column A and B in Excel, on the drug and placebo box, the candidate , The evaluator and the analyst remain unaware of the type of intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committ of Birjand University of Medical Scieces
Street address
Hospital Razi, Gaffari street
City
Birjand
Province
South Khorasan
Postal code
9717844471
Approval date
2021-03-05, 1399/12/15
Ethics committee reference number
IR.BUMS.REC.1399.521

Health conditions studied

1

Description of health condition studied
Hypoxia due the mechanism of Covid-19
ICD-10 code
U07.1
ICD-10 code description
Covid 19

Primary outcomes

1

Description
Atrial of Oxygen saturation
Timepoint
Before the intervention and 48 hours,72 hours after the start of intervention
Method of measurement
Cardiac monitoring

2

Description
Measure of Arterial blood oxygen
Timepoint
Before the intervention and 48 hours,72 hours after the start of intervention
Method of measurement
ABG

3

Description
Blood pressure
Timepoint
Before the intervention and 48 hours,72 hours after the start of intervention
Method of measurement
Cardiac monitoring

Secondary outcomes

1

Description
Duration of hospitalization in Intensive care unit
Timepoint
Daily
Method of measurement
Check list

Intervention groups

1

Description
Intervention group: The intervention group will receive standard treatment. In addition The intervention group will receive 400 mg oral pentoxifylline tablets made in Iran, Farabi Pharmaceutical Company with generic code 00970, three times a day (every 8 hours) for 72 hours
Category
Treatment - Drugs

2

Description
Control group: the control group will receive standard treatment. In addition will receive placebo. The placebo prepared by Farabi Pharmaceutical Company will be taken orally three times a day (every 8 hours) for 72 hours.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Mahmoud Gangifard
Street address
Gaffari street
City
Birjand
Province
South Khorasan
Postal code
9717844471
Phone
+98 56 3162 2275
Fax
+98 56 3238 1128
Email
fardganj@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Farshid Abedi
Street address
Gaffari street
City
Birjand
Province
South Khorasan
Postal code
9717844471
Phone
+98 56 3244 3041
Fax
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Email
abedif@bums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Farshid Abedi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases

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Gaffari street
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Mahmoud Ganjefard
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Arbabpoor
Position
Nurse
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
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009832626000
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Email
rajab.arbabpor@bums.ac.ir

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
Some of the information obtained will be available based on change in initial out comes.
When the data will become available and for how long
Start of access period 6 month after production and publication of results.
To whom data/document is available
People engaged in medical universities of the country.
Under which criteria data/document could be used
The methods and data contained in this clinical trial should be used solely to advance similar projects.it is also necessary to mention the research center of this study (Birjand university of medical sciences)
From where data/document is obtainable
Dr Mahmoud Gnjifard,fardganj@gmail.com,Birjand university of medical sciences
What processes are involved for a request to access data/document
Contact the scientific or general respondent of the study Sending their official request to the respondent Apply the university Research council In case of a positive response from the council, It will be provided to the applicant in accordance with the ethics principles The total duration of the process from the time of receiving the request in 20 days.
Comments