

# 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 arbabbour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 56 3240 6421

##### Email address

rajab.arbabbor@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**

+98 56 3238 1128

##### **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

**Street address**

Gaffari street

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717844471

**Phone**

+98 56 3262 6000

**Fax**

+98 56 3238 1128

**Email**

abedif@mums.ac.ir

**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

**Street address**

Gaffari street

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717844471

**Phone**

+98 56 3262 6000

**Fax**

+98 56 3238 1128

**Email**

fardganj@gmail.com

**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**

Ghaffari Street

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717844471

**Phone**

009832626000

**Fax**

+98 56 3238 1128

**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 outcomes.

**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 Ganjifard, 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 is 20 days.

**Comments**