

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Investigating the effectiveness of pentoxifylline in diabetic patients with covid-19 : a clinical trial

#### Protocol summary

##### Study aim

Determining the effectiveness of pentoxifylline in diabetic patients with covid-19 hospitalized in Shahid Rahmonun Hospital, Yazd.

##### Design

A controlled, parallel-group, double-blind, randomized, phase 2 clinical trial on 100 patients. The rand function of Excel software was used for randomization.

##### Settings and conduct

At least 24 inpatient diabetic patients with COVID-19 over the age of 18 and receiving either pentoxifylline (400 mg three times a day) or dexamethasone (4 mg every 12 hours) will be studied. Improvement of patients is defined as arterial blood oxygen level of at least 93%, cessation of fever for 72 hours, and improvement of the general condition of patients. The levels of inflammatory markers, including serum interleukin 6, CRP, ESR, and ferritin, were checked in both groups at the beginning of the treatment and after one week from the start of the treatment. The person monitoring the patients will not be aware of the grouping done.

##### Participants/Inclusion and exclusion criteria

Patients: Having type 1 or 2 diabetes Infected with covid-19 Hospitalization in the non-specialized departments of Shahid Rahnamon Hospital, Yazd Age above 18 years

##### Intervention groups

In the pentoxifylline group, patients are treated with this drug at the rate of 400 mg three times a day, and in the opposite group, patients are only treated with intravenous administration of dexamethasone 4 mg every 12 hours.

##### Main outcome variables

Levels of inflammatory markers including serum interleukin 6, CRP, ESR, and ferritin

#### General information

##### Reason for update

##### Acronym

پنتوکسی فیلین در بیماران دیابتی مبتلا به کووید 19

##### IRCT registration information

IRCT registration number: **IRCT20190810044500N29**

Registration date: **2024-10-12, 1403/07/21**

Registration timing: **retrospective**

Last update: **2024-10-12, 1403/07/21**

Update count: **0**

##### Registration date

2024-10-12, 1403/07/21

##### Registrant information

###### Name

Fatemeh Saghafi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 35 3820 3419

###### Email address

f.saghafi@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-01-11, 1401/10/21

##### Expected recruitment end date

2023-04-09, 1402/01/20

##### Actual recruitment start date

2023-01-13, 1401/10/23

##### Actual recruitment end date

2023-04-19, 1402/01/30

##### Trial completion date

2023-04-19, 1402/01/30

##### Scientific title

Investigating the effectiveness of pentoxifylline in diabetic patients with covid-19 : a clinical trial

**Public title**

Evaluation of the efficacy of Pentoxiphyllin in hospitalized diabetic patients with Covid-19

**Purpose**

Health service research

**Inclusion/Exclusion criteria****Inclusion criteria:**

Diabetic patient with covid-19 hospitalized in non-specialized departments of teaching hospitals of Yazd University of Medical Sciences

**Exclusion criteria:****Age**

From **18 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **40**

Actual sample size reached: **47**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Each of the interventions was named with letters A and B, and the rand function of Excel software was used for randomization.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The outcome evaluator is blindfolded about the type of intervention.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Faculty of Ethics of Medical Sciences, Shahid Sadoughi University of Medical Sciences

**Street address**

Shahid Sadoughi University of Medical Sciences, Shohaday gomnam Blvd, Yazd

**City**

Yazd

**Province**

Yazd

**Postal code**

8915173143

**Approval date**

2023-01-11, 1401/10/21

**Ethics committee reference number**

IR.SSU.MEDICINE.REC.1401.198

**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**

IL6 marker level in serum

**Timepoint**

Weekly

**Method of measurement**

Blood test

**2****Description**

ESR marker level in serum

**Timepoint**

Weekly

**Method of measurement**

Blood test

**3****Description**

CRP marker level in serum

**Timepoint**

Weekly

**Method of measurement**

Blood test

**4****Description**

Ferritin marker level in serum

**Timepoint**

weekly

**Method of measurement**

Blood test

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Intervention group: In the pentoxifylline group, patients are treated with 400 mg three times a day with pentoxifylline.

### Category

Treatment - Drugs

## 2

### Description

Control group: Patients are only treated with intravenous administration of dexamethasone 4 mg every 12 hours

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Yazd teaching hospitals

#### Full name of responsible person

Fatemeh Sahafi

#### Street address

Shahid Ghandi Blvd

#### City

Yazd

#### Province

Yazd

#### Postal code

8915857958

#### Phone

+98 35 3822 4000

#### Email

saghafi.fa@gmail.com

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Yazd University of Medical Sciences

#### Full name of responsible person

dr amin salehi

#### Street address

The central building of Yazd University of Medical Sciences, Bahonar Square

#### City

Yazd

#### Province

Yazd

#### Postal code

9856783459

#### Phone

+98 35 3146 2056

#### Email

abargouei@gmail.com

#### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

Yes

### Title of funding source

Yazd University of Medical Sciences

### Proportion provided by this source

20

### 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

Yazd University of Medical Sciences

#### Full name of responsible person

Fatemeh saghafi

#### Position

Associate professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

critical care

#### Street address

Shahid Sadoughi University of Medical Sciences, Shohada gomnam Blvd

#### City

Yazd

#### Province

Yazd

#### Postal code

8915173143

#### Phone

+98 35 3820 3419

#### Email

sahafi.fa@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Yazd University of Medical Sciences

#### Full name of responsible person

Amin Salehi

#### Position

associate professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nutrition

#### Street address

The central building of Yazd University of Medical Sciences, Bahonar Square.

**City**

Yazd

**Province**

Yazd

**Postal code**

9856783459

**Phone**

+98 35 3146 2056

**Email**

abargouei@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Fatemeh Saghafi

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

critical care

**Street address**Shahid Sadoughi University of Medical Sciences,  
Shohada gomnam Blvd**City**

Yazd

**Province**

Yazd

**Postal code**

8915173143

**Phone**

+98 35 3820 3419

**Email**

saghafi.fa@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

After the analysis, the data are made available to others in the form of a scientific article

**When the data will become available and for how long**

Spring to summer 2024

**To whom data/document is available**

unlimited

**Under which criteria data/document could be used**

unlimited

**From where data/document is obtainable**

dr.fatemeh.saghafi@saghafi.fa@gmail.com

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

saghafi.fa@gmail.com

**Comments**