

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 addressShahid 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