

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Evaluation the role of pentoxifylline in erythropoietin-resistant anemia in hemodialysis patients

#### Protocol summary

##### Study aim

We aimed to evaluate the Pentoxifylline (PTX) effect on anemia and prescription erythropoietin (EPO) dose in hemodialysis (HD) patients.

##### Design

60 patients included into a randomized double blind parallel control trial study. We will randomize them into same size groups 30 cases of trial or PTX and control that receive placebo at the same time.

##### Settings and conduct

Participants will be recruited from among HD patients with anemia in HD center in Shiraz University of Medical Sciences, Shiraz, Iran. Each patient will be given an order number and received the medications in the corresponding prepacked bottles. Clinical investigators and patients will all masked to the treatment assignment.

##### Participants/Inclusion and exclusion criteria

Participants will be recruited from among HD patients with anemia in HD center in Shiraz University of Medical Sciences, Shiraz, Iran. Inclusion criteria : age of 18 years and more, receiving 4-hour HD treatments 3 times per week at least for 3 months, hemoglobin (Hb)<11 in at least 2 consecutive tests in a month, and no change in EPO dose for at least 1 month before starting the study. Exclusion criteria include blood transfusion due to any reason in recent 3 months.

##### Intervention groups

Each patient in the trial group will be received PTX (400mg twice a day for 12 weeks), and control group will be received starch tablet (placebo) for the same 12 weeks.

##### Main outcome variables

Hemoglobin, erythrocyte sedimentation rate, C-reactive protein

#### General information

##### Reason for update

#### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100413003698N2**  
Registration date: **2018-07-09, 1397/04/18**  
Registration timing: **retrospective**

Last update: **2018-07-09, 1397/04/18**

Update count: **0**

##### Registration date

2018-07-09, 1397/04/18

##### Registrant information

###### Name

Maryam Pakfetrat

###### Name of organization / entity

Shiraz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 176360453

###### Email address

pakfetratm@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-04-04, 1397/01/15

##### Expected recruitment end date

2018-07-06, 1397/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation the role of pentoxifylline in erythropoietin-resistant anemia in hemodialysis patients

**Public title**

The role of pentoxifylline in erythropoietin-resistant anemia

**Purpose**

Treatment

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

having the age of 18 years and more receiving HD treatments at least for 3 months receiving 4-hour HD treatments 3 times per week a hemoglobin (Hb)<11 in at least 2 consecutive tests in a month no change in EPO dose for at least 1 month before starting the study.

**Exclusion criteria:**

blood transfusion due to any reason in recent 3 months

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

We will collect 60 patients and randomized into same size groups of trial and control as blocking randomization used for allocation sequence.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Double-blind Each patient was given an order number and received the medications in the corresponding prepacked bottles. Patients and who will evaluate the outcome, do not aware of type of drugs.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethical committee of Shiraz University of Medical Sciences

**Street address**

floor7-Vice-Chancellery of Research -Shiraz University of Medical Sciences-Zand street-

**City**

Shiraz

**Province**

Fars

**Postal code**

7193635899

**Approval date**

2017-04-04, 1396/01/15

**Ethics committee reference number**

IR.SUMS.REC.1393. 747064

**Health conditions studied****1****Description of health condition studied**

Kidney dialysis

**ICD-10 code**

Y84.1

**ICD-10 code description**

Y84 Other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

**Primary outcomes****1****Description**

hemoglobin

**Timepoint**

at the beginning and the end of the study.

**Method of measurement**

blood samples will be drawn to measure of hemoglobin

**Secondary outcomes****1****Description**

erythrocyte sedimentation rate

**Timepoint**

at the beginning and the end of the study

**Method of measurement**

blood samples will be drawn

**2****Description**

C-reactive protein

**Timepoint**

at the beginning and the end of the study

**Method of measurement**

blood samples will be drawn

**Intervention groups****1****Description**

Intervention group: pentoxifylline. Each patient in the trial group will receive received PTX (400mg twice a day

for 12 weeks)

**Category**

Treatment - Drugs

**2**

**Description**

Control group: control group will receive starch tablet twice a day for 12 weeks

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Nemazi Hospital

**Full name of responsible person**

Maryam Pakfetrat

**Street address**

Zand street

**City**

Shiraz

**Province**

Fars

**Postal code**

7193635899

**Phone**

+98 71 3628 1563

**Email**

pakfetratm@sums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Ali Bahador

**Street address**

Zand street

**City**

Shiraz

**Province**

Fars

**Postal code**

۷۱۳۳۶ - ۷۱۳۴۸

**Phone**

+98 71 3233 2366

**Email**

bahadora@sums.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Maryam Pakfetrat

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Internal ward, Nemazi Hospital, Zand street, Shiraz

**City**

Shiraz

**Province**

Fars

**Postal code**

11351 - 71937

**Phone**

+98 71 3647 4332

**Email**

pakfetratm@sums.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Maryam Pakfetrat

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

floor6, Mohammad Rasool Allah Research Tower, Khalili street, Shiraz, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

۷۱۳۳۶ - ۷۱۳۴۸

**Phone**

+98 176360453

**Fax**

**Email**

snurc@sums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Maryam Pakfetrat

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

floor6, Mohammad Rasool Allah Research Tower,  
Khalili street, Shiraz, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

۷۱۳۴۸ - ۷۱۳۳۶

**Phone**

+98 176360453

**Fax**

**Email**

pakfetratm@sums.ac.ir

## 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

Undecided - It is not yet known if there will be 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