Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Evalution 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 recive 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
Evalution 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 collecte 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

۱۴۳۳۶ - 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

۱۴۳۳۶ - 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

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

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۱۴۳۳۶ - ۷۱۳۴۸

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+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