

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

Evaluation of the effect of pentoxifylline 400 mg on anemia control and decreasing the dose of erythropoietin in chronic hemodialysis patients

Protocol summary

Study aim

Determine the effect of pentoxifylline 400 mg on anemia control and decreasing the dose of erythropoietin in chronic hemodialysis patients

Design

Phase 3 controlled clinical trial, randomized by random blocks, with parallel groups, on 16 samples

Settings and conduct

Before the intervention, an initial assessment will be made. Then, the patients will be randomly assigned to two treatment and control groups by random block method. The intervention group will receive the 400 mg pentoxifylline pill once daily for 12 weeks. The control group, apart from the standard treatment that both groups receive (intravenous erythropoietin), will not have any additional intervention. The CRP test will be performed at the time of admission and after taking the medication. Also, hemoglobin level fluctuations of patients during the study will be followed up on monthly trials of patients and at the beginning and end of the study and if it increases to more than 11, the dose of erythropoietin will be reduced by 30% and, if continued less than 11, the doses of erythropoietin will increase by 30%. During the study, the side effects of the drug in patients including abdominal discomfort, gastrointestinal bleeding, gum bleeding and conjunctival hemorrhage will be evaluated and if they happen, patients will be excluded from the study. All steps of the research from intervention to clinical and paraclinical examinations will be done in Shahid Beheshti Hospital in Anzali.

Participants/Inclusion and exclusion criteria

Hemodialysis patients referring to Hemodialysis Center of Anzali Shahid Beheshti Hospital with anemia; GFR less than 15; hemodialysis in the last 3 months, as well as no history of hemorrhages and infections leading to hospitalization in a recent month are included in the study.

Intervention groups

Group 1: Intervention with 400 mg pentoxifylline pill,

made in Iran, once daily for 12 weeks and Group 2: control group (no medication). Both groups will receive an appropriate dosage of intravenous erythropoietin diagnosed by physician

Main outcome variables

Anemia control; reducing the need for intravenous erythropoietin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180122038471N1**

Registration date: **2018-02-08, 1396/11/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-08, 1396/11/19**

Update count: **0**

Registration date

2018-02-08, 1396/11/19

Registrant information

Name

Pegah Aghajanzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3352 5259

Email address

paghajanzadeh@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-05, 1396/10/15

Expected recruitment end date

2018-05-05, 1397/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of pentoxifylline 400 mg on anemia control and decreasing the dose of erythropoietin in chronic hemodialysis patients

Public title
The effect of pentoxifylline 400 mg on anemia control and decreasing the dose of erythropoietin

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 GFR less than 15 Have been under hemodialysis for at least 3 months Performing regular hemodialysis 3 times a week Having an iron saturation of more than 30% and ferritin more than 500 Dialysis adequacy criteria: Kt/V greater than 1/2 Have an arteriovenous fistula or a pacifier for hemodialysis Hemoglobin less than 11 in at least 2 consecutive tests within a month
Exclusion criteria:
 History of bleeding in a recent month History of infection leading to hospitalization in a recent month Use of theophylline and androgens Intolerance to drug use in oral form Patient dissatisfaction The patient has undergone blood transfusion or B12 administration for any reason during the last 3 months. The presence of any underlying illness that justifies anemia, including thyroid and parathyroid dysfunction, hemoglobinopathy and malnutrition, and ... Hemorrhagic retinopathy The presence of coronary artery disease in the last 3 months

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: 16

Randomization (investigator's opinion)
Randomized

Randomization description
Using the random block method

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

Opposite the 17th Shahrivar Hospital, Ciadati Ave, Namjoo St.

City

Rasht

Province

Guilan

Postal code

41446-66949

Approval date

2017-12-30, 1396/10/09

Ethics committee reference number

IR.GUMS.REC.1396.419

Health conditions studied

1

Description of health condition studied

Anemia

ICD-10 code

D46.4

ICD-10 code description

Refractory anemia, unspecified

Primary outcomes

1

Description

Hemoglobin level

Timepoint

At the beginning of the study (before the intervention) and 4, 8 and 12 weeks after the intervention

Method of measurement

Blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 400 mg pentoxifylline pill, made in Iran, once daily for 12 weeks, with an appropriate dosage of intravenous erythropoietin for each patient diagnosed by physician

Category

Treatment - Drugs

2**Description**

Control group: Routine care and no additional intervention with an appropriate dosage of intravenous erythropoietin for each patient diagnosed by physician

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hemodialysis Center of Shahid Beheshti Hospital, Anzali

Full name of responsible person

Pegah Aghajanzadeh

Street address

Shahid Beheshti Hospital, Kalivar 2 St., Anzali

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Urology Research Centre, Guilan University of Medical Sciences

Full name of responsible person

Dr. Siavsh Falahatkar

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Grant name

10506

Grant code / Reference number

32

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

Yes

Title of funding source

Urology Research Centre, Guilan 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**

Rasht University of Medical Sciences

Full name of responsible person

Samira Rahimi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Samaneh Esmaeili

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Non-faculty researcher

Latest degree

Master

Other areas of specialty/work

Urology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

All patient information is confidential and their publication is not ethically correct. Information will only be published in the form of report or/and scientific paper.

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

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

Yes - There is a plan to make this available

Title and more details about the data/document

All information, study protocol, results, forms and ... will be published in the form of scientific paper.

When the data will become available and for how long

One month after the publication of the article, it will start to be available.

To whom data/document is available

All researchers in Iran who are affiliated with one of the academic or research institutes approved by the Ministry of Health and Medical Education.

Under which criteria data/document could be used

In case of doing Cohort studies or multicentre studies by other eligible researchers

From where data/document is obtainable

Dr. Pegah Aghajanzadeh, executor of project and Dr. Siavash Falahtakar, Head of Urology Research Center
Address: Urology Research Center, Razi Hospital, Rasht
Phone: 013- 33525259

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

Submitting a written request for the head of the Urology Research Center, stating the request to the project executive other colleagues and getting their approval, writing a written opinion to the applicant, taking the moral obligation of the applicant, sending the data and documentation to the applicant

Comments