# 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
**Street address**
Razi Hospital, Sardar Jangal Street
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falahatkar_s@yahoo.com
**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

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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**

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Urology Research Center, Guilan University of Medical Sciences

**Full name of responsible person**
Samaneh Esmaeili

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Non-faculty researcher

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Master

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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**