

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### Effect of pentoxifylline on inflammatory factors and quality of life in hemodialysis patients

#### Protocol summary

##### Study aim

Effect of Pentoxifylline on inflammatory factors and quality of life in hemodialysis patients

##### Design

Randomized , Double blind , Clinical trial with control group , with parallel groups ,with 100 hemodialysis patients, based on previous studies.

##### Settings and conduct

Patients with chronic renal failure undergoing hemodialysis in the hemodialysis department of Emam Reza Hospital;None of the treatment staff and patients were aware of which patients received medication or placebo.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria:CRP>1;Age over 18 years; Initiate hemodialysis for at least 3 months and three times a week ;Ability to understand and sign a consent form; Properly functioning arteriovenous fistula or catheter ;Dialysis adequacy above 1.2 Exclusion criteria:Pregnancy ;The presence of any chronic,active,uncontrolled or severe chronic inflammatory disease(autoimmune disease,connective tissue disease,malignancy,HIV,liver disease and pulmonary disease) ;The presence of chronic infection or the occurrence of acute infection in a recent month; Hemoglobin is less than 10g/dL ;Concurrently presence in another trial(drug or supplement) ;A medical history(such as heart attack or brain injury)or surgical in the last 3 months ;Symptoms of malabsorption; Bleeding disorders(Includes coagulopathies)or high risk of bleeding; Change in diet in the last 1 month ;Abuse of alcohol and other substances that cause dependence

##### Intervention groups

Intervention group: The treatment group consists of 50 patients receiving 400 mg orally of Pentoxifylline daily for 3 months

##### Main outcome variables

serum level of TNF- $\alpha$  serum level of CRP Quality of life score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170609034406N3**

Registration date: **2019-09-21, 1398/06/30**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-09-21, 1398/06/30**

Update count: **0**

##### Registration date

2019-09-21, 1398/06/30

##### Registrant information

##### Name

Afshin Gharekhani

##### Name of organization / entity

Faculty of Pharmacy/Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3334 1315

##### Email address

gharekhanian@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-04-21, 1398/02/01

##### Expected recruitment end date

2020-04-20, 1399/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Effect of pentoxifylline on inflammatory factors and quality of life in hemodialysis patients

**Public title**

Effect of pentoxifylline on inflammatory factors and quality of life in hemodialysis patients

**Purpose**

Supportive

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

CRP>1 Age over 18 years Initiate hemodialysis for at least 3 months and three times a week Ability to understand and sign a consent form Properly functioning arteriovenous fistula or catheter Dialysis adequacy above 1.2

**Exclusion criteria:**

Pregnancy The presence of any chronic, active, uncontrolled or severe chronic inflammatory disease (autoimmune disease, connective tissue disease, malignancy, HIV, liver disease and pulmonary disease) The presence of chronic infection or the occurrence of acute infection in a recent month Hemoglobin is less than 10g/dL Concurrently presence in another trial (drug or supplement) A medical history (such as heart attack or brain injury) or surgical in the last 3 months Symptoms of malabsorption Bleeding disorders (includes coagulopathies) or high risk of bleeding Change in diet in the last 1 month Abuse of alcohol and other substances that cause dependence

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, Permuted Block Randomization method was used for entering patients in control and treatment groups. In this method, each block contained an equal number of treatment groups and control group. Random numbers in this study were given using the Excel program to determine random blocks and random groups.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This study is conducted in a single blind clinical trial. None of the people distributing drugs and patients are aware of which patients receive the drug or placebo, and are only diagnosed with the numbers given by the system to the patients.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics Committee of Tabriz University of Medical Sciences

**Street address**

No 2 central building, Tabriz University of Medical sciences, Golgasht Street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165665931

**Approval date**

2019-02-25, 1397/12/06

**Ethics committee reference number**

IR.TBZMED.REC.1397.954

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

End Stage Renal Disease

**ICD-10 code**

N18.5

**ICD-10 code description**

Chronic kidney disease, stage 5

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

serum level of TNF- $\alpha$

**Timepoint**

Before intervention. At the end of the intervention

**Method of measurement**

ELISA kit

**2****Description**

serum level of CRP

**Timepoint**

Before intervention. At the end of the intervention

**Method of measurement**

ELISA kit

## Secondary outcomes

### 1

#### Description

Quality of life

#### Timepoint

Before intervention. At the end of the intervention

#### Method of measurement

Standard questionnaire

## Intervention groups

### 1

#### Description

Intervention group: The treatment group consists of 50 patients receiving 400 mg orally of Pentoxifylline daily for 3 months

#### Category

Treatment - Drugs

### 2

#### Description

Control group consisted of 50 patients receiving 400 mg orally of placebo(which apart from the active ingredient,were similar to Pentoxifylline tablets )daily for 3 months

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza Hospital

##### Full name of responsible person

Afshin Gharekhani

##### Street address

Golgasht street

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5147663419

##### Email

gharekhanian@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr abolghasem Jouyban

#### Street address

Center of Tabriz Medical University,Daneshgah St,  
Tabriz,Iran

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

51656-65811

#### Phone

+98 41 3335 7310

#### Fax

+98 41 3336 3231

#### Email

ajouyban@hotmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Afshin Gharekhani

##### Position

Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Medical Pharmacy

##### Street address

Faculty of Pharmacy , Tabriz University of Medical  
Science , Daneshgah Street , Tabriz , Iran

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##### Province

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##### Postal code

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##### Phone

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##### Email

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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**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Lachin Rezaoust

**Position**

Pharmacy Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Medical Pharmacy

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**Province**

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**Postal code**

5147663419

**Phone**

+98 41 3230 5153

**Email**

lachinrzdst@yahoo.com

## 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**

There is no further information

**Study Protocol**

Yes - There is 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**

Yes - There is 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**

Demographic data and main outcomes will be shared

**When the data will become available and for how long**

Data files will become available 6 months after publication

**To whom data/document is available**

It will be only available for people working in academic institutions

**Under which criteria data/document could be used**

All of the data can be freely used if the citation is appropriately considered

**From where data/document is obtainable**

The applicants will be referred to research Vice-chancellor

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

All of the requested data should be mentioned in a application letter which will be sent to the Research Vice-chancellor of Tabriz University of Medical Sciences.

**Comments**