

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jun 2026

### The effect of Pentoxifylline on C reactive protein level and dialysis adequacy in end stage renal disease patients under hemodialysis

#### Protocol summary

2014-01-28, 1392/11/08

##### Summary

purpose of study: The effect of pentoxifylline on C reactive protein level (an acute phase reactant) and dialysis adequacy in end stage renal disease patients under hemodialysis structure of study: randomized, double blind, control with placebo Patients referred to dialysis institute of Valiasr Hospital after matching for Age, Sex and Time that patients were under dialysis, randomly sent in two groups of drug and placebo. Patients and dialysis institute staff were not aware of which group is drug group and which one is placebo group. inclusion criteria: acceptance of written consent; End Stage Renal Disease; more than 15year; BMI between 15 - 35 exclusion criteria: pentoxifylline use before study; no acceptance of written consent; abnormal LFT; hyper sensitivity reaction to pentoxifylline; active infection; recent malignancy; depression; recent ICH; recent retinal hemorrhage; dialysis period under 3 month. population of study: end stage renal disease patients under hemodialysis referred to Valiasr hospital. number of population of study: 80 patients. intervention of study: The effect of pentoxifylline on C reactive protein level (an acute phase reactant) and dialysis adequacy time of study: one month consumption of Pentoxifylline primary results: decrease in serum CRP level and increase in dialysis adequacy

##### Registrant information

###### Name

Pardis ketabi Moghaddam

###### Name of organization / entity

Amiralmomenin hospital

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3417 3601

###### Email address

dr.ketabimoghadam@arakmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Arak University of Medical Sciences

##### Expected recruitment start date

2014-03-21, 1393/01/01

##### Expected recruitment end date

2015-02-20, 1393/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Pentoxifylline on C reactive protein level and dialysis adequacy in end stage renal disease patients under hemodialysis

##### Public title

The effect of Pentoxifylline on C reactive protein level and dialysis adequacy

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: acceptance of written consent; End

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2013120715695N1**

Registration date: **2014-01-28, 1392/11/08**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

Stage Renal Disease; more than 15year; BMI between 15 - 35 Exclusion criteria: pentoxifylline use before study; no acceptance of written consent; abnormal LFT; hyper sensitivity reaction to pentoxifylline; active infection; recent malignancy; depression; recent ICH; recent retinal hemorrhage; dialysis period under 3 months

#### Age

From **15 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **80**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Arak University of Medical Sciences

##### Street address

Pardis Site, Bbasij Square, Arak

##### City

Arak

##### Postal code

3848176941

#### Approval date

2013-09-23, 1392/07/01

#### Ethics committee reference number

92-148-12

## Health conditions studied

### 1

#### Description of health condition studied

esrd

#### ICD-10 code

N18.5

#### ICD-10 code description

Chronic kidney Disease, stage 5

### 2

#### Description of health condition studied

Ischemic Heart Disease

#### ICD-10 code

I20-I25

#### ICD-10 code description

Angina pectoris, Acute myocardial infarction, Subsequent myocardial infarction, Certain current complications following acute myocardial infarction, Other acute ischaemic heart diseases, Chronic ischaemic heart disease,

## Primary outcomes

### 1

#### Description

CRP

#### Timepoint

before and after receiving placebo or drug

#### Method of measurement

quantitative kit of CRP

## Secondary outcomes

### 1

#### Description

Dialysis Adequacy

#### Timepoint

before and after dialysis and before and after receiving placebo or drug

#### Method of measurement

$KT/V: K ( \text{cc/min} ) \times \text{time} ( \text{min} ) / \text{urea volume} ( \text{cc} )$

## Intervention groups

### 1

#### Description

Pentoxifylline Tab 400 mg daily 30 days in Intervention group

#### Category

Treatment - Drugs

### 2

#### Description

Starch Tab daily in Control group

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dialysis Institute of Valiasr Hospital

##### Full name of responsible person

Pardis Ketabi Moghaddam

**Street address**

Valiasr Hospital, Sardaran Square, Arak

**City**

Arak

<http://www.arakmu.ac.ir>

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

Amiralmomenin Hospital

**Full name of responsible person**

Dr Parvin Soltani

**Position**

Nephrologist

**Other areas of specialty/work****Street address**

Amiralmomenin Hospital, Basij Square, Arak

**City**

Arak

**Postal code**

3848176941

**Phone**

+98 86 3417 3601

**Fax**

+98 34173630

**Email**

[dr.ketabimoghadam@arakmu.ac.ir](mailto:dr.ketabimoghadam@arakmu.ac.ir)

**Web page address**

<http://www.arakmu.ac.ir>

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

Arak University of Medical Sciences

**Full name of responsible person**

Miss Jahani

**Street address**

Research and Education Site, Arak Medical University,

Basij Square, Arak

**City**

Arak

**Grant name****Grant code / Reference number**

933

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

Yes

**Title of funding source**

Arak University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

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

Amiralmomenin Hospital

**Full name of responsible person**

Dr. Afsaneh Talayi

**Position**

Internist, Endocrinologist

**Other areas of specialty/work****Street address**

Amiralmomenin Hospital, Basij Square, Arak

**City**

Arak

**Postal code**

3848176941

**Phone**

+98 86 3417 3601

**Fax**

+98 34173630

**Email**

[amoozesh@arakmu.ac.ir](mailto:amoozesh@arakmu.ac.ir)

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Amiralmomenin Hospital

**Full name of responsible person**

Dr Pardis Ketabi Moghaddam

**Position**

Internal Medicine Assistant

**Other areas of specialty/work****Street address**

Amiralmomenin Hospital, Basij Square, Arak

**City**

Arak

**Postal code**

3848176941

**Phone**

+98 86 3417 3601

**Fax**

+98 34173630

**Email**

[dr.ketabimoghadam@arakmu.ac.ir](mailto:dr.ketabimoghadam@arakmu.ac.ir)  
[gh\\_nyx@yahoo.ac.ir](mailto:gh_nyx@yahoo.ac.ir)

**Web page address**

<http://www.arakmu.ac.ir>

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*