

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)

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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

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

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

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

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<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

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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

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n**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