

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparing the effect of Pentoxifylline on serum concentrations of C-Reactive Protein (CRP) in hemodialysis patients

Protocol summary

Summary

The aim of this study was to compare the effect of PTX vs placebo on serum concentrations of C-Reactive Protein (CRP) in patients on hemodialysis. All ESRD patients of Ali ibn Abi Talib's hemodialysis ward that at least 2 months underwent hemodialysis treatment were selected. 54 patients were randomly allocated to an intervention or a control group. Patients of the intervention group received one PTX tablet (400 mg) once a day, whereas controls received one placebo. All patients had three hemodialysis sessions per week, each session take 4 hours. Clinical evaluations were performed just after intervention and then as monthly. Serum samples of both group at 0, 2 and 4 months, for measuring CRP concentrations taken and delivered to laboratory. Also laboratory results were recorded in patients' history forms. All laboratory measurements were performed in a specific laboratory to minimize the error. To eliminate the source of bias in this study, patients were balanced with regard to disease, age and gender. Finally, the results of two groups compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016032722540N2**

Registration date: **2016-05-13, 1395/02/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-13, 1395/02/24

Registrant information

Name

Iman Poorkeykhaei

Name of organization / entity

Zahedan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3341 3396

Email address

iman.poorkeykha@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zahedan University of Medical Sciences

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2015-10-07, 1394/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Pentoxifylline on serum concentrations of C-Reactive Protein (CRP) in hemodialysis patients

Public title

Pentoxifylline effect in serum C-Reactive Protein (CRP) Concentration level in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Arteriovenous fistula as vascular access, Hemodialysis patients at least 2 months prior trial. Exclusion criteria: Chronic active liver disease, Any infectious disease 2 months before the study, Failed kidney graft, Hypersensitivity to PTX or other methylxanthines, Hemorrhage/clotting disorders, Risk for

worsening pre-existing cardiac arrhythmias or arterial hypotension, Treatment with antibiotics, non-steroidal anti-inflammatory drugs, steroids, immunosuppressives, statins or PTX 3 months previous to the study

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Zahedan University of Medical Sciences

Street address

Khalij Fars highway - Zahedan University of Medical Sciences

City

Zahedan

Postal code

Approval date

2014-06-22, 1393/04/01

Ethics committee reference number

6836

Health conditions studied

1

Description of health condition studied

End stage renal disease patients who underwent hemodialysis treatment

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

Serum CRP concentrations

Timepoint

At 0, 2 and 4 months of intervention

Method of measurement

Serum CRP concentrations

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: Pentoxifylline: PTX tablet (400 mg) orally once a day

Category

Treatment - Drugs

2

Description

Control: One starch tablet once a day

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemodialysis ward of Ali ibn Abi Talib hospital in zahedan

Full name of responsible person

Dr Ali Alidadi

Street address

Khalij Fars highway - Ali ibn Abi Talib hospital

City

Zahedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Mohsen Taheri

Street address

Khalij Fars highway - Ali ibn Abi Talib hospital

City

Zahedan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan 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**

Zahedan University of Medical Sciences

Full name of responsible person

Dr Ali Alidadi

Position

Nephrologist

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

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Zahedan University of Medical Sciences

Full name of responsible person

Dr Reza Golabci-Fard

Position

Residence of internal medicine

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Fax**Email****Web page address****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