

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Effect of pentoxifylline on inflammatory and biochemical markers of hemodialysis patients

Protocol summary

Study aim

Appointment of effect of pentoxifylline on inflammatory and biochemical markers of hemodialysis patients

Design

This RCT study is conducted on 50 hemodialysis patients who referred to the hemodialysis ward of Shahid Beheshti hospital in Yasuj city. Patients randomly (Random Permuted Blocks) were divided in to intervention(3 month pentoxifylline) and control(without drug) group respectively.

Settings and conduct

This study was conducted on hemodialysis patients referring to hemodialysis center of Shahid Beheshti Hospital, Yasuj.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged>18 years; patients who were dialysed at least three times per week for a 3 month period. Exclusion criteria: Liver disease, malignancy, AIDS; patients who have active infectious disease in previous 2 month ; kidney transplantation; blood disorders; cardiac arrhythmia; patient who take NSAID and steroids; immune deficiency; taking pentoxifylline in previous 3 month

Intervention groups

In a 3 month period, intervention group patients take 400 mg pentoxifylline once daily, and control group patient observed without drug.

Main outcome variables

IL-6, IL-10, TNF-a, CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150622022869N6**

Registration date: **2018-02-07, 1396/11/18**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-07, 1396/11/18**

Update count: **0**

Registration date

2018-02-07, 1396/11/18

Registrant information

Name

Moslem Sedaghattalab

Name of organization / entity

Yasuj University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 74 3322 0163

Email address

m.sedaghattalab@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Yasuj University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pentoxifylline on inflammatory and biochemical markers of hemodialysis patients

Public title

Effect of pentoxifylline on inflammatory and biochemical markers of hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged >18 years Patients who were dialysed at least three times per week for a 3 month period Presence of well vascular access Written and conscious satisfaction

Exclusion criteria:
Liver disease, malignancy, AIDS Patients who have active infectious disease in previous 2 month Allergy to pentoxifylline and other methylxanthines Kidney transplantation Blood disorders Cardiac arrhythmia Hypotention Taking NSAID and steroids Immune deficiency; Taking pentoxifylline in previous 3 month

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Random Permuted Blocks was used for randomization with blocks of size of 4 that after every 4 patients there was an equal number assigned to each treatment. For each block, one of the arrangements (CCII, CICI, ICCI, IICC, ICIC, CIIC) was randomly chosen (C= Control, I= Intervention).

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 Yasuj University of Medical Science

Street address

Yasuj University of Medical Science, Motahari street, Yasuj city

City

Yasuj

Province

Kohgiluyeh-va-Boyerahmad

Postal code

75917-41417

Approval date

2016-08-04, 1395/05/14

Ethics committee reference number

IR.YUMS.REC.1396.85

Health conditions studied

1

Description of health condition studied

End stage kidney disease

ICD-10 code

N18.5

ICD-10 code description

Chronic kidney disease, stage 5

Primary outcomes

1

Description

IL-6

Timepoint

before intervention and 3 months after intervention

Method of measurement

ELISA

2

Description

IL-10

Timepoint

before intervention and 3 months after intervention

Method of measurement

ELISA

3

Description

TNF- α

Timepoint

before intervention and 3 months after intervention

Method of measurement

ELISA

4

Description

CRP

Timepoint

before intervention and 3 months after intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

Drug reaction

Timepoint

3 months after intervention
Method of measurement
Questionnaire

Intervention groups

1

Description

Intervention: Pentoxifylline tablet 400 mg every nights for 3 month

Category

Treatment - Drugs

2

Description

Control: usual supervision

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemodialysis ward of Shahid Beheshti hospital

Full name of responsible person

Moslem Sedaghatalab

Street address

Montazeri St, Shahid Beheshti Hospital

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moslem.sedaghatalab@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Yasuj University of Medical Sciences

Full name of responsible person

Hossein Mary Oryad

Street address

Yasuj University of Medical Sciences, Motahari street, Yasuj city

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Email

oryad.hossein@yums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Yasuj 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

Yasuj University of Medical Sciences

Full name of responsible person

Moslem Sedaghatalab

Position

Assistant professor, Internist

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

Emam Sajad hospital, Dr.Jalil street, Yasuj city

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yasuj University of Medical Sciences

Full name of responsible person

Moslem Sedaghatalab

Position

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Latest degree

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

Some data such as major outcomes will be sharing.

When the data will become available and for how long

1398

To whom data/document is available

collegiate institution

Under which criteria data/document could be used

only above instances

From where data/document is obtainable

Valiollah Talebi valitalebi.md@gmail.com

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

After sending e-mail

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Yasuj University of Medical Sciences

Full name of responsible person

Moslem Sedaghattalab

Position

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