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 medocation 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 disaese 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 sergical 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-α 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)

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+98 41 3334 1315

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gharekhania@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 disaese 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 sergical 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-α

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
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5147663419
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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
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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
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Person responsible for updating data

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

Comments