

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of the effects of combination therapy of pentoxifylline and losartan in comparison with losartan alone on diabetic nephropathy

Protocol summary

Study aim

Investigate the effects of combined pentoxifylline with angiotensin receptor inhibitor in diabetic nephropathy

Design

Sixty DM type 2 patients with urinary albumin / creatinine ratio > 300 mg / g were included in the study. The randomization method is simple allocation (coin toss) and the randomization unit is individual. The clinical trial will consist of two intervention groups: losartan treatment with pentoxifylline and control group: losartan treatment. This study is a single-blind, randomized trial.

Settings and conduct

Patients with DM2 treated with insulin and oral agent who have been referred to endocrinology or nephrology clinic of Vali-e-Asr Hospital in Zanjan due to albuminuria and who have no contraindication to use pentoxifylline enter the study. Patients will be blinded so they won't know the type of group they will be in.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Type 2 diabetes treated with insulin and oral medication with GFR above 30 and albuminuria above 300 mg / g despite receiving losartan during the last three months. Non-inclusion criteria: patient dissatisfaction; Type 1 diabetes; Hypersensitivity to pentoxifylline; GFR <30; pregnancy.

Intervention groups

Intervention group: Add pentoxifylline to losartan (losartan 50 mg twice daily and pentoxifylline 400 twice daily) for 3 months. Control group: Continue treatment with losartan alone (losartan 50 mg twice daily) for 3 months.

Main outcome variables

Albuminuria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190806044451N2**

Registration date: **2021-01-09, 1399/10/20**

Registration timing: **retrospective**

Last update: **2021-01-09, 1399/10/20**

Update count: **0**

Registration date

2021-01-09, 1399/10/20

Registrant information

Name

Farzane Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3377 0758

Email address

metabolic1397@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-13, 1398/04/22

Expected recruitment end date

2020-06-11, 1399/03/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of combination therapy of pentoxifylline and losartan in comparison with losartan alone on diabetic nephropathy

Public title

Efficacy of Pentoxifylline in diabetic nephropathy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Type 2 diabetic patients treated with insulin and oral agents GFR above 30 cc / min / 1.73 m2 albuminuria above 300 mg/g
Exclusion criteria:
Patient dissatisfaction Type 1 diabetes Pentoxifylline allergy Chronic heart failure Uncontrolled hypertension Other medicines that affect albuminuria Cerebral hemorrhage Extensive retinal hemorrhage ESRD, GFR <30 Pregnancy Hyperkalemia (high potassium) 5.5 before or during the study)

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method in this study is simple randomization and the randomization unit is also individual. Subjects in this study will be divided into control (losartan treatment) and intervention (losartan treatment with pentoxifylline) groups using coin throwing (coin toss) method.

Blinding (investigator's opinion)
Single blinded

Blinding description
This study is single blind and the patient will be explained about the cause of administration and the effect and side effects of the prescribed drug. The two groups will not be in relationship with each other and the the name of pentoxifylline will not be said to the control group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zanjan University of Medical

Sciences
Street address
Metabolic diseases research center, Vali-e-asr hospital, Sheikh Fazlollah street
City
Zanjan
Province
Zanjan
Postal code
4515613191
Approval date
2019-07-13, 1398/04/22
Ethics committee reference number
IR.ZUMS.REC.1398.158

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

2

Description of health condition studied

Diabetic Nephropathy

ICD-10 code

N00-N08

ICD-10 code description

بیماریهای گلوмерولی

Primary outcomes

1

Description

Random Urin Albumin/Creatinine

Timepoint

3 months before intervention and before starting pentoxifylline and 3 months after starting pentoxifylline

Method of measurement

Lab test

Secondary outcomes

1

Description

Creatinin

Timepoint

Before starting pentoxifylline and 3 months after starting pentoxifylline

Method of measurement

Lab test

2

Description

Hemoglobin A1c
Timepoint
Before starting pentoxifylline and 3 months after starting pentoxifylline
Method of measurement
Lab test

3

Description
Blood pressure
Timepoint
Before starting pentoxifylline and 3 months after starting pentoxifylline
Method of measurement
Sphygmomanometer

4

Description
Body mass index
Timepoint
Before starting pentoxifylline and 3 months after starting pentoxifylline
Method of measurement
meter & Balance

5

Description
Fasting blood sugar (FBS)
Timepoint
Before starting pentoxifylline and 3 months after starting pentoxifylline
Method of measurement
Lab test

6

Description
Pentoxifylline Complications
Timepoint
Before starting pentoxifylline and 3 months after starting pentoxifylline
Method of measurement
History taking

Intervention groups

1

Description
Intervention group: Add oral Pentoxifylline 400 mg (twice daily) to oral Losartan 50 mg (twice daily) for 3 months.
Category
Treatment - Drugs

2

Description
Control group: Continue treatment with oral Losartan 50 mg twice daily for 3 months
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Somayeh Jalali
Street address
Metabolic diseases researchs center, Valiasr Hospital, Shariati blvd
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somayehjalali10@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr Alireza Shoghli
Street address
Metabolic diseases researchs center, Valiasr hospital, Shariati blvd , Zanjan
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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
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Somayeh Jalali
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Internal Medicine
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Metabolic diseases research center ,Valiasr hospital,
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Person responsible for updating data

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metabolic1397@gmail.com

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

No - There is not a plan to make this available

Title and more details about the data/document

All potential data can be shared after making people
unidentifiable

When the data will become available and for how long

Start access period 3 months after publishing the results

To whom data/document is available

It will only be available to researchers working in
academic and scientific institutions

Under which criteria data/document could be used

With the written and official permission of the researcher
or supervisor, access to all documents will be possible

From where data/document is obtainable

Contact those in charge through these numbers
09146592655- 02433770758. Email:
somayehjalali10@yahoo.com. Corresponding Address:
Metabolic Disorders Research Center, Valiasr Hospital,
Zanjan, Iran

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

1) Contact the person in charge or the researcher and

coordinate. 2) Submit request by email or letter. This

may take at least a month to access the data.
Comments