

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Effects of pentoxifylline on serum markers of diabetic nephropathy in patients with type2 diabetes

Protocol summary

Study aim

To assess effects of pentoxifylline on serum copeptin, osteopontin, cystatin C, HSP70, bilirubin, uric acid, adiponectin, resistin, hs-CRP, TNF α , Apo A, Apo B and the urinary albumin excretion (UAE) rate in patients with type 2 diabetes with nephropathy.

Design

This is a randomized double-blind clinical trial study on 70 patients with type2 diabetes with proteinuria in two groups randomly; including pentoxifylline add on losartan and control group with increasing dose of losartan. Drugs will prescribe to each group for 12 weeks.

Settings and conduct

This is a randomized clinical trial study on patients with type2 diabetes. patients will be randomly divided into 2 groups. Before treatment and after 12 week blood samples will be taken. All samples will be analyzed by standard methods. This study will be conducted at diabetes clinic of the vali-asr hospital in Tehran University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with type2 diabetes with proteinuria. Exclusion criteria are infectious or malignant diseases, non-diabetic kidney disease, retinal hemorrhage, acute myocardial infarction or unstable angina, history of cardiocerebrovascular or peripheral artery disease, uncontrolled hypertension (i.e., systolic blood pressure [SBP] \geq 140mmHg and/or diastolic blood pressure [DBP] \geq 90 mmHg), pregnancy, anemia, hyperthyroidism, history of hemodialysis, baseline serum potassium concentrations \geq 5.5 meq/L, estimated glomerular filtration rate (eGFR) $<$ 30mL/minute/1.73 m and pentoxifylline intolerance.

Intervention groups

patients with type2 diabetes with proteinuria in two groups including pentoxifylline add on losartan or increased dosage of losartan

Main outcome variables

serum copeptin, osteopontin, cystatin C, HSP70, bilirubin, uric acid, adiponectin, resistin, hs-CRP, TNF α , Apo A, Apo B and the urinary albumin excretion (UAE) rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121104011356N10**

Registration date: **2020-04-14, 1399/01/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-14, 1399/01/26**

Update count: **0**

Registration date

2020-04-14, 1399/01/26

Registrant information

Name

Alireza Esteghamati

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-03, 1399/01/15

Expected recruitment end date

2020-06-04, 1399/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of pentoxifylline on serum markers of diabetic nephropathy in patients with type2 diabetes

Public title

Effects of pentoxifylline diabetic nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

type2 diabetes according to American Diabetes Association (ADA 2019) with proteinuria

Exclusion criteria:

infectious or malignant diseases non-diabetic kidney disease retinal hemorrhage acute myocardial infarction or unstable angina history of cardio-cerebro-vascular or peripheral artery disease uncontrolled hypertension (i.e., systolic blood pressure [SBP] \geq 140mmHg and/or diastolic blood pressure [DBP] \geq 90 mmHg) pregnancy anemia hyperthyroidism history of hemodialysis baseline serum potassium concentrations \geq 5.5 meq/L estimated glomerular filtration rate (eGFR) $<$ 30mL/minute/1.73 m and pentoxifylline intolerance

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

patients will be randomized with random table number.

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 National Institute for Medical

Research Development

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No 21, Besat Ave, West Fatemi Blvd, Tehran

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۱۴۱۹۶۹۳۱۱۱

Approval date

2019-08-25, 1398/06/03

Ethics committee reference number

IR.NIMAD.REC.1398.193

Health conditions studied**1****Description of health condition studied**

diabetic nephropathy

ICD-10 code

E11.21

ICD-10 code description

Type 2 diabetes mellitus with diabetic nephropathy

Primary outcomes**1****Description**

Copeptin

Timepoint

before treatment and after 12 weeks

Method of measurement

Copeptin will be measured using a quantitative sandwich ELISA immunoassay

2**Description**

osteopontin

Timepoint

before treatment and after 12 weeks

Method of measurement

Osteopontin will be measured using a quantitative sandwich ELISA

3**Description**

cystatin c

Timepoint

before treatment and after 12 weeks

Method of measurement

cystatin c will be measured using a quantitative sandwich ELISA

4**Description**

HSP70

Timepoint

before treatment and after 12 weeks

Method of measurement

HSP70 will be measured using a quantitative sandwich ELISA

5

Description

Bilirubin

Timepoint

before treatment and after 12 weeks

Method of measurement

Bilirubin will be measured using an enzymatic assay

6

Description

Uric acid

Timepoint

before treatment and after 12 weeks

Method of measurement

Uric acid will be measured using an enzymatic assay

7

Description

Apo A

Timepoint

before treatment and after 12 weeks

Method of measurement

Apo A will be measured using a quantitative sandwich ELISA

8

Description

Apo B

Timepoint

before treatment and after 12 weeks

Method of measurement

Apo B will be measured using a quantitative sandwich ELISA

9

Description

adiponectin

Timepoint

before treatment and after 12 weeks

Method of measurement

Adiponectin will be measured using a quantitative sandwich ELISA

10

Description

Resistin

Timepoint

before treatment and after 12 weeks

Method of measurement

Adiponectin will be measured using a quantitative sandwich ELISA

11

Description

hs-CRP

Timepoint

before treatment and after 12 weeks

Method of measurement

hs-CRP will be measured using a quantitative sandwich ELISA

12

Description

TNF α

Timepoint

before treatment and after 12 weeks

Method of measurement

TNF α will be measured using a quantitative sandwich ELISA

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: pentoxifylline 400 mg daily for 12 week

Category

Treatment - Drugs

2

Description

Control group: increasing dose of losartan 50 mg daily for 12 week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-Asr Hospital

Full name of responsible person

Professor Alireza Esteghamati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

National Institute for Medical Research Development

Full name of responsible person

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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

National Institute for Medical Research Development

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**

Tehran University of Medical Sciences

Full name of responsible person

manouchehr nakhjavani

Position

professor

Latest degree

Subspecialist

Other areas of specialty/work

endocrinology and metabolism

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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

Given the confidentiality of the information of the patients participating in this study, I do not intend to publish the participants' data files.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available