Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Effect of pentoxifylline as an intervention to reduce proteinuria in patients with type 2 of diabetes treated with angiotensin system blockers compared with patients (control group) were treated with ACEI or ARB

Protocol summary

Summary

In this study effect of pentoxifylline, a drug nonselective phosphodiesterase inhibitor, will be measured in patients with diabetes to reduce urinary protein excretion. 32 patients because of proteinuria with type 2 of diabetic chosen or have been admitted from endocrinology and nephrology clinic and divided into two groups. Their questionnaire, including demographic data and etc. will be filled. In Group (1) ACEI and ARB medications used to reduce proteinuria. In the group (2) ACEI and ARB drugs in addition, pentoxifylline. Finally, the results of the two groups in terms of further reduction in proteinuria compared. Patients will be eligible for this prospective study, i.e., they have more than 500 milligrams protein in 24-hour urine excretion and do not have contra-indications of PTX (cerebral hemorrhage, retinal hemorrhage, acute myocardial infarction and hypotension). During the study will not change in glycemic control and treatment plan and if they are taking hypertension medication, drugs will continue unchanged. Baseline patient's blood pressure was measured twice within 10 minutes and fasting blood sugar, U/A, creatinine and urine protein will be tested in 24 hours. Then patients are divided to two groups, half of the patients treat with PTX, ACEI and ARB and half of patients treat with ARB and ACEI for 2 months randomly and Finally clinical and laboratory evaluations will be repeated. Inclusion criteria: patients with type 2 of diabetes; proteinuria greater than 500 mg per 24 hours; people who are treated with ACEI and ARB; patients who do not have contra-indications of PTX. Exclusion criteria: proteinuria less than 500 mg per 24 hours; people who had a history of retinal hemorrhages; who had a history of MI; patients who have contra-indications of PTX; those treated with ACEI and ARB not; people who have hypotension

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111827097N2**
Registration date: **2016-12-01, 1395/09/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-12-01, 1395/09/11

Registrant information

Name

Dr Faramarz Darghahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3351 2000

Email address

mj.naghizadeh@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

The Ardabil University of Medical Science

Expected recruitment start date

2016-11-30, 1395/09/10

Expected recruitment end date

2017-02-28, 1395/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of pentoxifylline as an intervention to reduce proteinuria in patients with type 2 of diabetes treated with angiotensin system blockers compared with patients (control group) were treated with ACEI or ARB

Public title
Effect of pentoxifylline in reducing proteinuria in patients with type 2 of diabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patients with type 2 of diabetes; proteinuria greater than 500 mg per 24 hours; people who are treated with ACEI and ARB; patients who do not have contra-indications of PTX. Exclusion criteria: proteinuria less than 500 mg per 24 hours; people who had a history of retinal hemorrhages; who had a history of MI; patients who have contra-indications of PTX; those treated with ACEI and ARB not; people who have hypotension

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **32**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ardebil University of Medical Sciences

Street address
Ardebil University of Medical Sciences, University street, Ardabil, Iran

City
Ardebil

Postal code

Approval date
2016-10-30, 1395/08/09

Ethics committee reference number
IR.ARUMS.REC.1395.56

Health conditions studied

1

Description of health condition studied
Diabete

ICD-10 code
N08.3

ICD-10 code description
Diabetic nephropathy

Primary outcomes

1

Description
Proteinuria

Timepoint
befor and after the study

Method of measurement
mg/d

Secondary outcomes

1

Description
Urea

Timepoint
befor and after the study

Method of measurement
mg/dl

Intervention groups

1

Description
Case group: Pentoxifylline, Tablet 400mg oral BD for 2 month Losartan, Tablet 50mg oral OD for 2 month Captopril, Tablet 50mg oral BD for 2 month

Category
Treatment - Drugs

2

Description
Control group: Losartan, Tablet 50mg oral OD for 2 month Captopril, Tablet 50mg oral BD for 2 month

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomini Hospital

Full name of responsible person

Dr Shadab Mirfakhrayi

Street address

City

Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ardebil University of Medical Sciences

Full name of responsible person

Dr Manochehr Iranparvar

Street address

Ardebil University of Medical Sciences, University street, Ardabil, Iran

City

Ardabil

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ardebil 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

Ardebil University of Medical Sciences

Full name of responsible person

Dr Shadab Mirfakhrayi

Position

Internal Medicine Assistant

Other areas of specialty/work

Street address

Imam khomini hospital, Ardabil, Iran

City

Ardabil

Postal code

Phone

+98 45 3351 2006

Fax

Email

shadabmirfakhrayi@icloud.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardebil University of Medical Sciences

Full name of responsible person

Dr Shadab Mirfakhrayi

Position

Internal Medicine Assistant

Other areas of specialty/work

Street address

Imam Khomini Hospital, Ardabil, Iran

City

Ardabil

Postal code

Phone

+98 45 3351 2006

Fax

Email

shadabmirfakhrayi@icloud.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ardebil University of Medical Sciences

Full name of responsible person

Dr Shadab Mirfakhrayi

Position

Internal Medicine Assistant

Other areas of specialty/work

Street address

Ardebil University of Medical Sciences, University street, Ardabil, Iran

City

Ardabil

Postal code

Phone

+98 45 3351 2006

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