

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Effect of pentoxifylline on proteinuria of diabetic type 2 patients

Protocol summary

Summary

The aim of this randomized, single center, double blind, and placebo controlled study is to assess the effect of pentoxifylline on proteinuria in type 2 diabetic patients. A total of 54 type 2 diabetic patients with proteinuria of more than 500 mg per day treated with ACEI at least for 3 months referred to polyclinic in Shahid Beheshti Hospital, and private clinics of Babol are enrolled and assigned into intervention group receiving Pentoxifylline, 1200 mg per day for 3 months or control group receiving placebo. Proteinuria will be measured and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201010144941N1**
Registration date: **2010-12-01, 1389/09/10**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-12-01, 1389/09/10

Registrant information

Name

Farshid Oliaei

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research, Babol University of Medical Sciences

Expected recruitment start date

2010-11-22, 1389/09/01

Expected recruitment end date

2011-07-23, 1390/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pentoxifylline on proteinuria of diabetic type 2 patients

Public title

Effect of pentoxifylline on proteinuria of diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diabetics type 2 with proteinuria more than 500 mg /d under treatment with ACEI for at least 3 months Exclusion criteria: diabetics type 1, creatinin more than 1.5 mg/dl, systolic blood pressure more than 140 mmHg, Patients on hemodialysis, presence of fever, acute respiratory distress, or acute heart failure, non-diabetic proteinuric glomerulopathies, obstructive urinary stones, confirmed hypersensitivity to caffeine, theophylline or pentoxifylline, recent brain or retinal hemorrhage, recent 3 months use of thiazolidinediones

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: 54

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

Babol University of Medical Sciences

Street address

Ganjafruz ave., Babol

City

Babol

Postal code

Approval date

2009-12-18, 1388/09/27

Ethics committee reference number

9397

Health conditions studied

1

Description of health condition studied

Diabetes Mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus, type II

Primary outcomes

1

Description

Proteinuria

Timepoint

before and after intervention

Method of measurement

24 hours urinary protein measurement

Secondary outcomes

1

Description

serum creatinine

Timepoint

Before and after the intervention

Method of measurement

serum cratinine measurement by jaffe method

Intervention groups

1

Description

Control group: placebo as similar tablets 3 times daily oral for 3 months

Category

Placebo

2

Description

Intervention group: pentoxifylline tablet 400 mg 3 times daily orally for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Private clinic

Full name of responsible person

Street address

City

Babol

2

Recruitment center

Name of recruitment center

Nephrology clinic of Shahid Beheshti hospital

Full name of responsible person

Street address

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Amrollah Mostafazadeh

Street address

Vice- chancellery for research, Babol University of Medical Sciences, Ganj Afruz Ave.

City

Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Dr. Farshid Oliaee

Position

nephrologist- academic member

Other areas of specialty/work

Street address

Shahid Beheshti Hospital- Shahid Sargord Ghasemi Ave.- Shahid Keshvari square- Babol

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Farshid Oliaee

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City

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Phone

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Email

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Web page address

Person responsible for updating data

Contact

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