

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Short-Term Effects of Lovastatin Therapy on Proteinuria of Type 2 Diabetic Nephropathy

Protocol summary

Summary

The main aim of the present study was to evaluate short-term effects of Lovastatin Therapy on proteinuria of type 2 diabetic nephropathy. This was a quasi clinical trial with treatment and withdrawal periods carried out at Drug Applied Research Center of Tabriz University of Medical University. Men with clinically documented T2DN were enrolled. To eliminate potential confounding factors, we only included patients with type 2 diabetes mellitus and proteinuria levels lower than the nephrotic range (< 3 g/d) whose estimated glomerular filtration rate (eGFR) was higher than 30 mL/min/1.73m². The plasma glucose and blood pressure of the participants was controlled by standard drugs lacking confounding effect when needed. All of the patients were under their own regular restricted protein diet. Exclusion criteria included: the use of 3-hydroxy-3-methylglutaryl coenzyme A antagonists, fibrates, aspirin, β -blockers, allopurinol, vitamins, pentoxifylline, fish oil, other antioxidant drugs consumed in the previous three months, active smoking, chronic inflammation, active coronary artery disease in the previous three months (diagnosed by symptoms and electrocardiography), and poorly controlled diabetes mellitus. Samples were drawn before lovastatin therapy (of 20 mg/d; Ghazal Co, Tehran, Iran), after 45 days of lovastatin therapy, after 90 days of lovastatin therapy, and 30 days after the withdrawal of lovastatin therapy. Serum creatinine (Cr) and urea were determined using standard methods. eGFR was calculated using the Modification of Diet in Renal Disease (MDRD) formula. Twenty-four hour urine samples, Cr, and protein levels were assessed using colorimetric and immunoturbidimetric methods.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012073010446N1**

Registration date: **2012-08-08, 1391/05/18**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-08-08, 1391/05/18

Registrant information

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Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Drug Applied Research Center, Tabriz University (Medical Sciences), Tabriz, Iran.

Expected recruitment start date

2006-02-01, 1384/11/12

Expected recruitment end date

2008-03-31, 1387/01/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Short-Term Effects of Lovastatin Therapy on Proteinuria of Type 2 Diabetic Nephropathy

Public title

Effects of Lovastatin on Proteinuria of Diabetic Nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Men with clinically documented T2DN were enrolled. To eliminate potential confounding factors, we only included patients with type 2 diabetes mellitus and proteinuria levels lower than the nephrotic range (i.e., < 3 g/d) whose estimated glomerular filtration rate (eGFR) was higher than 30 mL/min/1.73m² (as calculated by the Modification of Diet in Renal Disease formula). The fasting plasma glucose (FPG) of the participants was controlled by insulin injection and/or administration of oral sulfonylurea. Blood pressure (BP) was maintained at less than 129/79 mm Hg with treatment by angiotensin-converting enzyme inhibitors (ACEI) and/or angiotensin receptor blockers (ARB), with α -blockers and diuretics when needed. All of the patients were under their own regular restricted protein diet (\leq 0.8 g/kg/d), as prescribed by a nutrition consultant. Any major changes in blood pressure, protein intake, or physical activity during the study period were considered as withdrawal criteria. Exclusion criteria included: the use of 3-hydroxy-3-methylglutaryl coenzyme A (HMG-CoA) antagonists, fibrates, aspirin, β -blockers, allopurinol, vitamins, pentoxifylline, fish oil, other antioxidant drugs consumed in the previous three months, active smoking, chronic inflammation (such as diabetic foot, hepatitis, infection, etc.), active coronary artery disease in the previous three months (diagnosed by symptoms and electrocardiography), and poorly controlled diabetes mellitus (Hb-A1c > 7.5%).

Age

From **40 years** old to **70 years** old

Gender

Male

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features

This was a quasi clinical trial with treatment and withdrawal periods

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethics Committee of Tabriz University of Medical Sciences

Street address

Research Vice of Tabriz University (Medical Sciences), Tabriz University, Tabriz, Iran.

City

Tabriz

Postal code**Approval date**

2005-08-23, 1384/06/01

Ethics committee reference number

8516

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

Proteinuria of Type 2 Diabetic Nephropathy

ICD-10 code

N08.3 -E11

ICD-10 code description

Glomerular disorders in diabetes mellitus

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

Change in Proteinuria level

Timepoint

(A) before lovastatin therapy (baseline), (B) after 45 days of lovastatin therapy (46th day), (C) after 90 days of lovastatin therapy (91st day), and (D) 30 days after the withdrawal of lovastatin therapy (121st day).

Method of measurement

eGFR was calculated using the Modification of Diet in Renal Disease (MDRD) formula. Twenty-four hour urine samples, Cr, and protein levels were assessed using colorimetric and immunoturbidimetric methods.

Secondary outcomes

empty

Intervention groups**1****Description**

Lovastatin (Ghazal Co, Tehran, Iran), in a dose of 20 mg/d, was administered to the patients for 90 days. At the end of the third month, the patients were asked to stop lovastatin intake from the 91st day until the 120th day.

Category

Treatment - Drugs

Clinical Pharmacy Laboratory, Drug Applied Research Center, Tabriz University (Medical Sciences), Pashmineh, Daneshgah Street.

Recruitment centers

1

Recruitment center

Name of recruitment center

Drug Applied Research Center

Full name of responsible person

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Researcher, MD

Other areas of specialty/work

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Drug Applied Research Center

Full name of responsible person

Dr. Hossein BaBaie

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Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Drug Applied Research Center

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

Drug Applied Research Center, Tabriz University (Medical Sciences),

Full name of responsible person

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Researcher, MD

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Position

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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