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 cratinine (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 coulorimetric 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

Name

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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 (≤ 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 coulorimetric 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

Recruitment centers

1

Recruitment center

Name of recruitment center
Drug Applied Research Center

Full name of responsible person
Dr. Nariman Nezami

Street address
Drug Applied Research Center, pashmineh, daneshgah Street, Tabriz , Iran

City
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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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Drug Applied Research Center, Tabriz University (Medical Sciences), Pashmineh, Daneshgah Street,

City
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

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Other areas of specialty/work

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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