

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effects of atorvastatin on proteinuria of type 2 diabetic nephropathy in patients with history of gestational diabetes mellitus

Protocol summary

Summary

In present study effect of atorvastatin will be investigated in patients with diabetic nephropathy with a history of gestational diabetes by examining proteinuria and renal function. First, 42 patients attending at Emam Reza educational clinical center of Tabriz University of Medical Sciences , who are between 20 to 65 years old, with type 2 diabetes mellitus , history of gestational diabetes mellitus, proteinuria levels lower than 3 g/d and estimated glomerular filtration rate more than 30 mL/min/1.73m² will be included, and patients with history of use of antioxidant drugs consumption in past 6 months, active smoking, active coronary artery disease in the previous 6 months, diabetic foot, hepatitis, and poorly controlled diabetes will be excluded from study. Then the patients will be divided into two equal intervention and control groups using RandList software. Atorvastatin 10 mg per day will be administered to the patients in the intervention group for 90 days. At the end of the third month, the patients will be asked to stop atorvastatin intake for a month. Meanwhile, for control group exact protocol will be administered using placebo instead of atorvastatin. The main outcomes of the present study include lipid profile, serum creatinine, serum uric acid level and urine protein which will be examined before the intervention and 90 days after intervention. Then the results in these stages will be compared in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100918946N4**

Registration date: **2016-11-30, 1395/09/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-11-30, 1395/09/10

Registrant information

Name

Reza Piri

Name of organization / entity

Emam Reza educational-medical center, Tabriz
University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 5372

Email address

reza.piri@rocketmail.com

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-10-01, 1393/07/09

Expected recruitment end date

2016-10-01, 1395/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of atorvastatin on proteinuria of type 2 diabetic nephropathy in patients with history of gestational diabetes mellitus

Public title

Effects of atorvastatin on diabetic nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients between 20 to 65 years old; patients with type 2 diabetes mellitus; history of gestational diabetes mellitus; proteinuria levels lower than 3 g/d (nephrotic range); estimated glomerular filtration rate more than 30 mL/min/1.73m2 Exclusion criteria: use of fibrates, statins antagonists, aspirin, allopurinol, β-blockers, pentoxifylline, fish oil, other antioxidant drugs consumption in past 6 months; active smoking; active coronary artery disease in the previous 6 months; diabetic foot; hepatitis; poorly controlled diabetes (Hb-A1c more than 7.5%)

Age

From **20 years** old to **65 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **42**

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz university of medical sciences, Golgasht street, Azadi avenue.

City

Tabriz

Postal code

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

9/6/911

Health conditions studied

1

Description of health condition studied

Diabetic nephropathy

ICD-10 code

E10.2

ICD-10 code description

Insulin-dependent diabetes mellitus with renal complications

Primary outcomes

1

Description

Lipid profile

Timepoint

Before intervention, 90 days after intervention initiation

Method of measurement

Blood sample

2

Description

Serum creatinine

Timepoint

Before intervention, 90 days after intervention initiation

Method of measurement

Blood sample

3

Description

Serum uric acid

Timepoint

Before intervention, 90 days after intervention initiation

Method of measurement

Blood sample

4

Description

Urine Protein

Timepoint

Before intervention, 90 days after intervention initiation

Method of measurement

Blood sample

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Atorvastatin 10 mg per day will be administered to the patients in intervention group for 90 days. At the end of the third month, patients will be asked not to use Atorvastatin for a month.

Category

Treatment - Drugs

2

Description

Control group: Daily Placebo will be administered to the patients in control group for 90 days. At the end of the third month, patients will be asked not to use placebo for a month.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza medical-educational centre, Tarbiz
University of medical sciences

Full name of responsible person

Dr.Parviz Saleh

Street address

Emam Reza educational-medical centre, Golgasht
street, Azadi Avenue

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of
Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Rashidi

Street address

Azadi street, Golgasht Avenue, Central campus of
Tabriz university of medical science

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz 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

Emam Reza educational-medical center

Full name of responsible person

Dr.Parviz Saleh

Position

Associate professor of tropical and infectious diseases

Other areas of specialty/work

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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