Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Therapeutic effects of atorvastatin on blood sugar, insulin resistance and inflammatory mediators in patients with diabetes type 2

Protocol summary

Summary

The aim of this study is assessment the therapeutic effects of atorvastatin on blood sugar control, decreasing insulin resistance and inflammatory markers in patient with diabetes type two. In this study 88 patients with diabetes type 2 who had Hb A1C less than 9, triglyceride less than 250, low density lipoprotein between 70 to 160, high density lipoprotein more than 35, total cholesterol less than 240 and are treated with oral hypoglycemic agents. Patients are excluded if there were evidence of diabetes complications such as retinopathy, nephropathy and Glomerular Filtration Rate less than 60, cardiovascular involvement such as Congestive Heart Failure,Ischemic Heart Diseases,Acute Myocardial Infarction during recent 1 year, history of epileptic disorders, history of significant active gastrointestinal diseases such as active peptic ulcer disease in recent 1 year, active significant hematologic , hepatic and musculoskeletal diseases. Patients who treated with insulin, got to acute illness, allergic history to statins, history of alcohol and opium consumption, breast feeder mothers and pregnant patients, have consumed statins during recent 6 months were also exculded. Patients divided into case and control group randomly and in case group the patients treated with atorvastatin 40mg per day for 12 weeks in addition to their medications and control group consumed placebo in addition to their medications. At the beginning of study both groups checked for Complete Blood Count,Alanine aminotransferase, Aspartate aminotransferase,Blood Urea Nitrogen,Creatinine,HbA1C, Fasting Blood Sugar,lipid profiles, Creatin phosphokinase, Lactate dehydrogenase, microalbuminurea, insulin, hsCRP, Tumor necrosis factor alpha, adiponektin and leptin and finally at the end of study all tested will be repeated and every changes in these tests will be analized.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108177358N1**
Registration date: **2012-08-22, 1391/06/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-08-22, 1391/06/01

Registrant information

Name
Mehdi Mahmudpour
Name of organization / entity
Arak University Of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 86 1417 3630
Email address
dr.mahmudpour@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University Of Medical Sciences

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Therapeutic effects of atorvastatin on blood sugar, insulin resistance and inflammatory mediators in patients with diabetes type 2

Public title
Effect of atorvastatin on blood sugar metabolism
Purpose
Treatment
Inclusion/Exclusion criteria
inclusion criteria: The patients with diabetes type 2 who had Hb A1C less than 9, triglyceride less than 250, low density lipoprotein (LDL) between 70 to 160, high density lipoprotein (HDL) more than 35, total cholesterol less than 240 and are treated with oral hypoglycemic agents. exclusion criteria: Evidence of diabetes complications such as retinopathy, nephropathy and Glomerular Filtration Rate(GFR) less than 60, cardiovascular involvement such as Congestive Heart Failure(CHF), Ischemic Heart Diseases(IHD), acute Myocardial Infarction (MI) during recent 1 year, history of epileptic disorders, history of significant active gastrointestinal diseases such as active peptic ulcer disease in recent 1 year, history of active significant hematologic , hepatic and musculoskeletal diseases , patients who treated with insulin, patients who affected to acute illness, allergic history to statins, history of alcohol and opium consumption, breast feeder mothers and pregnant patients, patients who have consumed statins during recent 6 months.
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **88**
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
Arak University Of Medical Sciences
Street address
Sardasht, Arak
City
Arak
Postal code
Approval date
2011-06-14, 1390/03/24
Ethics committee reference number
90-108-10

Health conditions studied

1

Description of health condition studied
Non-insulin-dependent diabetes mellitus
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
TNF-alpha
Timepoint
befor starting trial and 3 months later
Method of measurement
serologic methods

2

Description
hsCRP
Timepoint
befor starting trial and 3 months later
Method of measurement
serologic methods

3

Description
FBS
Timepoint
befor starting trial and 3 months later
Method of measurement
serologic methods

4

Description
Insulin
Timepoint
befor starting trial and 3 months later
Method of measurement
serologic methods

5

Description
Leptin
Timepoint
befor starting trial and 3 months later
Method of measurement
serologic methods

6

Description
Adiponektin
Timepoint
befor starting trial and 3 months later
Method of measurement
serologic methods

Secondary outcomes

1

Description
side effects on liver enzymes
Timepoint
befor starting trial and 3 months later
Method of measurement
serologic methods

2

Description
side effects on muscle enzymes
Timepoint
befor starting trial and 3 months later
Method of measurement
serologic methods

Intervention groups

1

Description
In control group 44 type two diabetic patients took placebo one capsul daily for 12 weeks in addition to their medications and tests performed at begining and after trial.
Category
Treatment - Drugs

2

Description
In case group 44 patients with type two diabetes mellitus took atorvastatin 40 miligram daily for 12 weeks in addition to their medications and tests performed at begining and after tial
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir-Al-Momenin hospital of Arak
Full name of responsible person
Dr.Mehdi Mahmudpour
Street address
Amir-Al-Momenin Hospital, Sardasht, Arak
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak university of medical sciences
Full name of responsible person
Dr.Saeed Changizi Ashtiyany
Street address
Department of research, Arak University Of Medical Sciences, Sardasht, Arak
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak university of medical sciences
Full name of responsible person
Dr.Mehdi Mahmudpour
Position
Resident of internal medicine
Other areas of specialty/work
Street address
Amir-Al-Momenin hospital
City
Arak
Postal code
Phone
+98 86 1417 3630

Fax
Email
mmahmudpour_59@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Assistant professor
Full name of responsible person
Dr.Afsane Talaeii
Position
Endocrinologist
Other areas of specialty/work
Street address
Amir-Al-Momenin hospital
City
Arak
Postal code
Phone
+98 86 1417 3630
Fax
Email
afsanehtalaeii@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Arak University Of Medical Sciences
Full name of responsible person
Dr.Mehdi Mahmudpour
Position
resident of internal medicine
Other areas of specialty/work
Street address
Amir-Al-Momenin Hospital
City
Arak
Postal code
Phone
+98 917 371 3799
Fax
Email
mmahmudpour_59@yahoo.com
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