

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Comparison of efficacy of low dose of Atorvastatin and Rosuvastatin versus high dose of Atorvastatin and Rosuvastatin in reducing hs-CRP and IL-6 in diabetic patient referred to the Institute of Endocrinology and Metabolism

Protocol summary

2019-01-10, 1397/10/20

Study aim

Efficacy of the low dose vs high dose of Atorvastatin and Rosuvastatin in reducing hs-CRP, IL-6 in diabetic patients.

Design

patients are randomized in to 4 groups each groups contain 25 diabetic patients: First group with Atorvastatin 20 mg daily 2th group with Atorvastatin 40 mg daily 3th group with Rosuvastatin 10 mg daily 4th group with Rosuvastatin 20 mg daily

Settings and conduct

Diabetic patients aged between 40 to 75 y/o referring to Institute Endocrinology and Metabolism are randomly categorize in different groups

Participants/Inclusion and exclusion criteria

Diabetic patients between 40 to 75 y/o

Intervention groups

Diabetic patients between 40-75 y/o

Main outcome variables

Highly Sensitive C-Reactive Protein , Interleukin 6

General information

Reason for update

Acronym

IL-6: Interleukin 6 hs-CRP:High sensitivity C-Reactive Protein

IRCT registration information

IRCT registration number: **IRCT20180929041169N2**

Registration date: **2019-01-10, 1397/10/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-10, 1397/10/20**

Update count: **0**

Registration date

Registrant information

Name

Mohammad taghi Gorji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8603 6064

Email address

malek.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of low dose of Atorvastatin and Rosuvastatin versus high dose of Atorvastatin and Rosuvastatin in reducing hs-CRP and IL-6 in diabetic patient referred to the Institute of Endocrinology and Metabolism

Public title

Comparison of efficacy of low vs. high dose of Atorvastatin and Rosuvastatin in reducing hs-CRP and IL-6 in diabetic patient referred to the Institute of

Endocrinology and Metabolism

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic patients who need to receive Statin according to ADA 2018

Exclusion criteria:

Pregnancy Patient with Genetic Disease Use of other lowering agent other than Statin Hx of Angina Hx of Nephropathy Hx of Hypothyroidism Hx of liver Disease or ALT> 3 ULN,AST>3 ULN CPK> 10 ULN Patients on Corticosteroids Patients with Cyclosporins or Hormone replacement therapy Hx of use of Alcohol Acute and chronic infectious or Inflammatory disease

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patient are Randomized in to 4 groups each groups contain 25 patients: First group with Atorvastatin 20 mg daily 2th group with Atorvastatin 40 mg daily 3th group with Rosuvastatin 10 mg daily 4th group with Rosuvastatin 20 mg daily

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of IRAN University of Medical Sciences

Street address

Iran University of Medical Sciences,Shahid Hemmat Highway,Tehran,IRAN

City

TEHRAN

Province

Tehran

Postal code

1449614535

Approval date

2018-08-26, 1397/06/04

Ethics committee reference number

IR.IUMS.REC..1397.196

Health conditions studied

1

Description of health condition studied

Efficacy of low dose and high dose Atorvastatin and Rusovastatin in Diabetic patients

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Measurement of highly sensitive C reactive protein & Interleukin-6

Timepoint

At the initial and 2 month after medication used

Method of measurement

Blood sampling with Elisa assay

Secondary outcomes

empty

Intervention groups

1

Description

Diabetic patients between 40 to 75 years old(no use of lower lipid drugs in past 2 month) are divided to four groups. Each group contains 25 patients. 1st group of intervention will receive 20 mg Atorvastatin (Abidi company) daily, after 2 months the level of IL-6 and hs-CRP will be measured and their decreased is compared between high and low intensity Statins.

Category

Treatment - Drugs

2

Description

Intervention group: 2nd group of intervention will receive 40 mg Atorvastatin (Abidi company) every day. After 2 months IL-6 and hs-CRP level will be measured and the decresed level of them will be compared between high and low intensity Statins.

Category

Treatment - Drugs

3

Description

Intervention group: 3rd group of intervention will receive

the daily dose of 10 mg Rosuvastatin (Abidi company) , and after 2 months IL-6 and hs-CRP level will be measured and compared between high and low intensity Statins, as well .

Category

Treatment - Drugs

4**Description**

Intervention group: 4th group of intervention will receive 20 mg Rosuvastatin for each day (Abidi company). The IL-6 and hs-CRP level of mentioned patients will be measured and compared between high and low intensity Statins, after 2 months.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Institute of Endocrinology and Metabolism affiliated to Iran University of Medical Sciences

Full name of responsible person

Mohamad Taghi Gorji

Street address

Institute of Endocrinology and Metabolism, No 10, Firoozeh Alley, Valieasr Avenue, Tehran

City

Tehran

Province

Tehran

Postal code

1593716615

Phone

+98 21 8603 6064

Fax

+98 21 8894 5173

Email

iem@iums.ac.ir

Web page address

http://iem.iums.ac.ir/

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr.Kazem Malakouti

Street address

Iran University of Medical Sciences, next to Milad Tower, Hemat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 86701

Fax

+98 21 8805 2248

Email

PR@iums.ac.ir

Web page address

http://iums.ac.ir/

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Mohamad Taghi Gorji

Position

Internist, Subspecialist Resident

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

No 10, Firoozeh alley, Valieasr avenue, Tehran

City

Tehran

Province

Tehran

Postal code

1593716615

Phone

+98 21 8603 6064

Fax

+98 21 8894 5173

Email

dr.hgorji@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences
Full name of responsible person
Mojtaba Malek
Position
Endocrinologist
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
No 10, Firoozeh alley, Valieasr avenue,Tehran
City
Tehran
Province
Tehran
Postal code
1593716615
Phone
+98 21 8603 6064
Fax
+98 21 8894 5173
Email
malek.m@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohamad Taghi Gorji
Position
Internist , Subspecialist Resident
Latest degree
Specialist
Other areas of specialty/work

Internal Medicine
Street address
No 10, Firoozeh Alley, Valieasr Avenue,Tehran
City
Tehran
Province
Tehran
Postal code
1593716615
Phone
+98 21 8603 6064
Fax
+98 21 8894 5173
Email
dr.hgorji@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable