Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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 sensivity 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
2019-01-10, 1397/10/20

Registrant information
Name
Mohammad taghi Gorji
Name of organization / entity
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Iran (Islamic Republic of)
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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

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TEHRAN

Province

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr.Kazem Malakouti

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

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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

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Person responsible for scientific inquiries

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Mojtaba Malek

Position

Endocrinologist

Latest degree

Subspecialist

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Latest degree

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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