

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effect of high dose versus low dose Atorvastatin therapy on inflammatory & coagulatory factors in type 2 diabetic patients

#### Protocol summary

##### Summary

This study is a randomized clinical trial to compare the effects of high-dose atorvastatin with low-dose atorvastatin on inflammatory markers and coagulation profiles in patients with type 2 diabetes. patients with type 2 diabetes over the age of 18 , LDL> 70 and TG <500 , patients are not treated with statins or Stopping the drug (>1 mth) , come to endocrine clinic of Imam Reza (AS) hospital were enrolled after consent . The sample size of this study, according to the results of the yicong, and colleagues study , Hs-CRP changes in the power 80 and a maximum Type I error of 0.05 was determined for each group of 93 samples to increase the validity of study , 100 patients for each group determined. The subjects were randomly divided into 2 groups of 100 people. In the first group, statins at high doses (40 mg) and low-dose statin group (10mg) administered. Initial tests : FBS, HbA1C, AST, ALT, ALP, BUN, Cr, TG, Total chol, LDL.HDL and specific tests: Homocysteine , fibrinogen and IL6 and IL1 done at baseline and then repeated 3 months. the effects of high-dose atorvastatin and low-dose atorvastatin after three months of education, on inflammatory factors and clotting factors are measured.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201502226710N5**  
Registration date: **2015-05-22, 1394/03/01**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-05-22, 1394/03/01

#### Registrant information

##### Name

Mitra Niafar

##### Name of organization / entity

Tabriz university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7850

##### Email address

niafarm@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

vice chancellor fo research,Tabriz university of Medical sciences

#### Expected recruitment start date

2014-11-22, 1393/09/01

#### Expected recruitment end date

2015-07-23, 1394/05/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of high dose versus low dose Atorvastatin therapy on inflammatory & coagulatory factors in type 2 diabetic patients

#### Public title

Effect of high dose versus low dose Atorvastatin therapy on inflammatory & coagulatory factors in type 2 diabetic patients

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: Patients with type2 diabetes mellitus

LDL>70 ; age>18y ;TG<500; patients who don't use or stopped statin use (> 1 mth) Exclusion criteria: type 1 diabetes Mellitus; chronic liver disease(liver enzymes more than 3 time the upper limit of normal , B or C Hepatitis ); renal failure Cr>2;pregnancy;lactation ; Chronic inflammatory diseases such as rheumatic diseases (rheumatoid arthritis and systemic lupus erythematosus); Patients with a history of anti-inflammatory drugs; In case of muscle pain and increased risk of rhabdomyolysis in patients with CPK elevation; unwillingness to participate in the study.

#### Age

From **18 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **200**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### 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 Tabriz University of Medical Sciences

##### Street address

Tabriz University of Medical Sciences, Daneshgah Sq

##### City

Tabriz

##### Postal code

#### Approval date

2015-02-09, 1393/11/20

#### Ethics committee reference number

93168

## Health conditions studied

### 1

#### Description of health condition studied

type 2 diabetic

#### ICD-10 code

E10,E11,E1

#### ICD-10 code description

Diabetes mellitus

## Primary outcomes

### 1

#### Description

low density Lipoprotein

#### Timepoint

At baseline and after 3 months of treatment

#### Method of measurement

Test

### 2

#### Description

cholesterol

#### Timepoint

At baseline and after 3 months of treatment

#### Method of measurement

test

## Secondary outcomes

### 1

#### Description

inflammatory markers

#### Timepoint

At baseline and after 3 months of treatment

#### Method of measurement

test

### 2

#### Description

coagulatory factor

#### Timepoint

At baseline and after 3 months of treatment

#### Method of measurement

test

## Intervention groups

### 1

#### Description

In the first group tablet Atorvastatin (40-80 milligram) daily will be prescribed

#### Category

Treatment - Drugs

### 2

#### Description

In the second group tablet Atorvastatin (10-20 milligram) daily will be prescribed

#### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Endocrine Clinic of Imam Reza hospital

**Full name of responsible person**

Dr. vahide Sadra

**Street address**

**City**

Tabriz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Tabriz University of Medical Sciences Daneshgah Square Tabriz

**Full name of responsible person**

Dr Rashidi

**Street address**

Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah Avenue,

**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 Daneshgah Square Tabriz

**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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mitra Niafar

**Position**

Endocrinology and Metabolism / Associate

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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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*