

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effectiveness of statins vs placebo on vascular endothelial function in patients with diastolic heart failure and normal coronary angiography

Protocol summary

Summary

The aim of this study is evaluation of Statin on vascular endothelial function in patients with diastolic heart failure and comparison of Flow Mediated Dilation with sonography (FMD) change in statin and placebo groups. Inclusion criteria are age above 18 years old; diastolic heart failure; normal coronary angiography and exclusion criteria are contraindication to statin therapy and absolute indication for statin therapy. The Study population include patients with diastolic heart failure according to Echocardiography without history or physical exam findings in favor to ischemic heart disease referred to echocardiography clinic of Imam and Golestan hospitals. the sample volume needed for intervention and placebo groups calculated 20 and in total 40. in intervention group each patient takes atorvastatin 20 mg daily and control group takes placebo for 8 weeks. At the ends of 8 weeks FMD change for each patient of both groups Will be measured and results will be compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010320538N1**

Registration date: **2015-06-15, 1394/03/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-06-15, 1394/03/25

Registrant information

Name

Ali Kardooni

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 3161

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences/School of Medicine

Expected recruitment start date

2014-11-01, 1393/08/10

Expected recruitment end date

2015-04-04, 1394/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of statins vs placebo on vascular endothelial function in patients with diastolic heart failure and normal coronary angiography

Public title

Evaluation of the effect of Statin on patient with heart failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age above 18y/o; diastolic heart failure; normal coronary angiography Exclusion criteria: contraindication to statin therapy; indication for statin

therapy according to 2013 AHA guideline for lipid management.

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ahvaz Jundishapur University of Medical Sciences ...

Street address

Golestan boluvarad

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Postal code**Approval date**

2015-01-31, 1393/11/11

Ethics committee reference number

AJUMS.REC.1393.414

Health conditions studied**1****Description of health condition studied**

Heart Failure

ICD-10 code

I50.1

ICD-10 code description

Left ventricular failure

Primary outcomes**1****Description**

Flow mediated diameter of brachial artery

Timepoint

Before and after intervention (8 weeks)

Method of measurement

Sonography test/Millimeters

Secondary outcomes**1****Description**

Lipid profile

Timepoint

After 8 week treatment

Method of measurement

Blood sample/ Mg/dl

Intervention groups**1****Description**

In control group 8 weeks treatment with placebo

Category

Treatment - Drugs

2**Description**

In intervention group 8 weeks treatment with atorvastatin 20 mg daily

Category

Treatment - Drugs

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

Imam khomeini hospital

Full name of responsible person

Ali kardooni

Street address

Azadegan st, Ahwaz

City

Ahwaz

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

Atherosclerosis Research Center

Full name of responsible person

Ataollah Ghadiri

Street address

Golestan hospital, Golestan st.

City

Ahvaz

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Atherosclerosis Research Center
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

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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