

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Preventive Effect of Atorvastatin 80 mg on Contrast Induced Nephropathy after Angiography in High Risk Patients

Protocol summary

Summary

We study the preventive effect of Atorvastatin on Contrast induced nephropathy after angiography in chronic kidney disease and diabetic patients. In this double blinded randomized clinical trial, 250 patients candidates for angiography with diabetes mellitus or chronic kidney disease and age of 55 to 75 years were included. Patients with previous contrast media administration during the last 10 days; Patients with chronic dialysis treatment ; recent treatment with Statin 80 mg and patients requiring emergency angiography were excluded. Patients were randomized to two groups receiving Atorvastatin (80 mg/day from 48hr before angiography) and placebo. All patients received intravenous isotonic saline and N-acetylcysteine. Variables such as hemoglobin and serum lipid profile and left ventricle ejection fraction are measured before the experiment. Before the intervention, 24 and 48 hours after the intervention, serum creatinine and BUN measured. Contrast induced nephropathy has been defined as an increasing serum creatinine more than 0.5mg/dl or more than 25% from the base.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120117413N9**

Registration date: **2014-12-15, 1393/09/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-12-15, 1393/09/24

Registrant information

Name

Hamidreza Karimi-Sari

Name of organization / entity

Student Research Committee, Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8126 4354

Email address

hrkarimisari@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Baqiyatallah medical science university

Expected recruitment start date

2013-01-20, 1391/11/01

Expected recruitment end date

2014-04-21, 1393/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preventive Effect of Atorvastatin 80 mg on Contrast Induced Nephropathy after Angiography in High Risk Patients

Public title

Preventive effect of atorvastatin in contrast nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diabetes mellitus (FBS> 126, Random BS> 200, GTT> 200); chronic renal failure (creatinine higher than 1.5 mg/dl or GFR less than 60) Exclusion criteria: recent treatment with statin 80 mg; patients requiring emergency angiography; contraindications to

prescribe statins; Patients with previous contrast media administration during the last 10 days; Patients with chronic dialysis treatment; patients with informed refusal of consent

Age

From **55 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **250**

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

Baqiyatallah medical science university ethic committee

Street address

Tehran

City

Tehran

Postal code

Approval date

2012-12-31, 1391/10/11

Ethics committee reference number

6821

Health conditions studied

1

Description of health condition studied

Contrast induced nephropathy

ICD-10 code

N14

ICD-10 code description

Drug- and heavy-metal-induced tubulo-interstitial and tubular conditions

Primary outcomes

1

Description

BUN

Timepoint

before-24 hr and 48 hr after intervention

Method of measurement

blood sampling

2

Description

creatinine

Timepoint

before-24 hr and 48 hr after intervention

Method of measurement

blood sampling

3

Description

HB

Timepoint

before intervention

Method of measurement

blood sampling

4

Description

LVEF

Timepoint

before intervention

Method of measurement

echocardiography

5

Description

lipid profile

Timepoint

before intervention

Method of measurement

blood sampling

6

Description

CIN

Timepoint

24 hr and 48 hr after intervention

Method of measurement

an increasing serum creatinine more than 0.5mg/dl or more than 25% from the base

Secondary outcomes

empty

Intervention groups

1

Description

For the case group from 48 hours before performing angiography Atorvastatin 80 mg/day and for the control group placebo was prescribed. Then all of case and control groups recieved isotonic saline and N-acetylcysteine.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah hospital

Full name of responsible person

Hesam sadat Hashemi

Street address

Baqiyatallah hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baqiyatallah university of medical science

Full name of responsible person

Gholam Hosein Alishiri

Street address

Tehran, molla sadra avenue

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Baqiyatallah university of medical science

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

Baqiyatallah university of medical science

Full name of responsible person

Hesam sadat Hashemi

Position

Medical student

Other areas of specialty/work

Street address

Baqiyatallah university

City

Tehran

Postal code

Phone

+98 21 7710 4021

Fax

Email

seyyedhesam.hashemi@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Baqiyatallah university

Full name of responsible person

Arezoo Khosravi

Position

assistant professor

Other areas of specialty/work

Street address

Tehran, Baqiyatallah hospital

City

Tehran

Postal code

Phone

00

Fax

Email

arekhosravi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Baqiyatallah university

Full name of responsible person

Hamidreza Karimi sari

Position

Medical student

Other areas of specialty/work

Street address

City

Postal code

Phone

Fax

Email

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