

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Rosuvastatin on the incidence of contrast nephropathy in patients with chronic renal failure receiving contrast

Protocol summary

Study aim

effect of Rosuvastatin in preventing decreased renal function in patients with chronic renal disease

Design

this is a clinical trial, randomized, blinded with a parallel group designed 350 chronic renal disease patients enrolled between February 2018 and March 2019 who are receive contrast media for CT scan.

Settings and conduct

patients who are refer for CT scan with contrast media to Alzahra hospital and have chronic kidney disease divide to 2 group with using random numbers. in intervention group, patients receive Rosuvastatin tablet 10 mg, 2 tablet one day before CT scan, 1 tablet just day of CT scan and 1 tablet one day after CT scan. in placebo group, placebo tablet with the same shape and manner like intervention group are giving.

Participants/Inclusion and exclusion criteria

Patients who have not history of statin use during 3 months ago, eGFR between 30-60 cc/min/1.73m², who are not pregnant, not receiving contrast media during 10 days ago and not using Metformin include in the study and if they die during 72 hours after using contrast media, acute coronary syndrome, have allergy to contrast media and end stage renal disease exclude from the study

Intervention groups

in intervention group, patients receive Rosuvostatin tablet 10 mg, manufactured by Abidi pharmaceutic, 2 tablet one day before CT scan , 1 tablet in the day of CT scan and 1 tablet 1 day after CT scan. in placebo group, Placebo tablet manufactured by Abidi pharmaceutic, with the same shape to intervention group and the same manner give them

Main outcome variables

creatinin measurement at baseline and after 48 hours of receiving contrast media

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090905002417N21**

Registration date: **2019-07-07, 1398/04/16**

Registration timing: **retrospective**

Last update: **2019-07-07, 1398/04/16**

Update count: **0**

Registration date

2019-07-07, 1398/04/16

Registrant information

Name

Firouzeh Moeinzadeh

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Rosuvastatin on the incidence of contrast nephropathy in patients with chronic renal failure receiving contrast

Public title

Effect of Rosuvastatin in contrast induced nephropathy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

absence of Statin use during past 3 months eGFR between 30 - 60 cc/min/1.73m² not pregnant absence use of contrast during past 10 days absence use of Metformin

Exclusion criteria:

Acute coronary syndrome history of allergy to contrast media death during 72 hours after receiving contrast media end stage renal disease

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **350**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization with random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

patients who are arrived in the study, the trained nurse who is directing patients into the study, investigator, data analyser

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2017-05-22, 1396/03/01

Ethics committee reference number

IR.mui.rec.1396.3.986

Health conditions studied

1

Description of health condition studied

Effect of Rosuvostatin in contrast induced nephropathy in chronic kidney disease

ICD-10 code

N18.3

ICD-10 code description

chronic kidney disease

Primary outcomes

1

Description

serum creatinin level

Timepoint

48 hours after contrast media use

Method of measurement

autoanalyser

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 175 patients is entered in study that they have chronic kidney disease and their eGFR are 30-60mg/dL. one day before contrast administration, they eat 2 tablet Rosuvastatin, Abidi pharmaceutic, IRAN. in the day of contrast administration and one day after that, they receive one tablet the same as before. 48 hours after contrast administration they undergo laboratory examination.

Category

Treatment - Drugs

2

Description

Control group: 175 patients is entered in study that they have chronic kidney disease and their eGFR are 30-60mg/dL. one day before contrast administration, they eat 2 tablet (placebo) Rosuvastatin, Abidi

pharmaceutic, IRAN. in the day of contrast administration and one day after that, they receive one tablet the same as before. 48 hours after contrast administration they undergo laboratory examination.

Category

Treatment - Drugs

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

Alzahra hospital

Full name of responsible person

Marziye Rezaei

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

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Full name of responsible person

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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

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Firouzeh Moeinzadeh

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Nephrology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

the shareable data contain points that will be published in the article.

When the data will become available and for how long

Starting 1 year after publication

To whom data/document is available

Available for academic investigators and industrial persons

Under which criteria data/document could be used

for more information contact us with email.

From where data/document is obtainable

contact with email

What processes are involved for a request to access data/document

maximum 1 year after sending your email we response you

Comments