

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Prophylactic effect of N-acetyl-cysteine plus Atorvastatin versus N-acetyl-cysteine and Atorvastatin alone for the prevention of contrast induced nephropathy in patients undergoing elective angiography with or without percutaneous coronary intervention: a single center prospective randomized controlled trial

Protocol summary

Study aim

Prophylactic role of NAC and Atorvastatin in preventing contrast induced nephropathy in patients undergoing angiography with or without PCI

Design

This single blind randomized controlled trial will be performed as a community-based and pragmatic control group with parallel groups.

Settings and conduct

This investigation included 250 participants admitting for elective coronary angiography with or without percutaneous coronary intervention in Ali-ebn Abitaleb Hospital, Shiraz, Iran. After being qualified for study entrance, the patients were obtained an informed consent and were randomly categorized in 4 groups. This study is also single blind, so patients do not notified whether they were in intervention or control group.

Participants/Inclusion and exclusion criteria

Eligible patients consist of individuals older than 21 years old with abnormal renal function (creatinine clearance between 15 and 60 mL/min or serum creatinine (SCr) ≥ 1.1 mg/dL) undergoing elective cardiac catheterization with or without PCI. Exclusion criteria: patients with end-stage renal failure (glomerular filtration rate (GFR) ≤ 15 mL/min); history of previous dialysis; pulmonary edema; emergency cardiac catheterization (patients with ST-segment elevation myocardial infarction undergoing primary PCI); exposure to contrast within previous two days ago before procedure; allergies to contrast media; liver disease and contraindication to statins.

Intervention groups

These individuals were randomly categorized in 4 groups with the following features: Group I (considered as control), Group II (statin 80 mg), Group III (NAC 1800 mg)

and Group IV (statin 80 mg plus NAC 1800 mg)

Main outcome variables

The primary outcome was serum creatinine alteration and the secondary clinical end point was incidence of CIN within 48 hours after contrast media exposure .

General information

Reason for update

Insufficient sample size of individuals with abnormal kidney function in this study and the start of new sampling of individuals with abnormal kidney function

Acronym

IRCT registration information

IRCT registration number: **IRCT20180417039347N1**

Registration date: **2018-11-20, 1397/08/29**

Registration timing: **prospective**

Last update: **2020-08-09, 1399/05/19**

Update count: **2**

Registration date

2018-11-20, 1397/08/29

Registrant information

Name

Saeed KESHTKAR

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3225 8032

Email address

s.keshtkar20@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prophylactic effect of N-acetyl-cysteine plus Atorvastatin versus N-acetyl-cysteine and Atorvastatin alone for the prevention of contrast induced nephropathy in patients undergoing elective angiography with or without percutaneous coronary intervention: a single center prospective randomized controlled trial

Public title

Prophylactic effect of N-acetyl-cysteine plus Atorvastatin versus N-acetyl-cysteine and Atorvastatin alone for the prevention of contrast induced nephropathy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Eligible patients include individuals older than 21 years old abnormal renal function (Creatinine clearance between 15 and 60 mL/min or serum creatinine (SCr) ≥ 1.1 mg/dL) Undergoing elective cardiac catheterization with or without PCI

Exclusion criteria:

Patients with end-stage renal failure (glomerular filtration rate (GFR) ≤ 15 mL/min), history of previous dialysis pulmonary edema emergency cardiac catheterization (patients with ST-segment elevation myocardial infarction undergoing primary PCI), exposure to contrast within previous two days ago before procedure allergies to contrast media, contraindication to statins liver disease

Age

From **21 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **250**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, random allocation method using variable blocks was used by statistical software for experimental and control groups

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, patients have been blinded about the intervention protocols .

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of zahedan university of medical science

Street address

Zahedan University of Medical Science, Dr Hesabi square, Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816737789

Approval date

2018-09-23, 1397/07/01

Ethics committee reference number

IR.ZAUMS.REC.1397.254

Health conditions studied

1

Description of health condition studied

Contrast induced nephropathy

ICD-10 code

T80.8

ICD-10 code description

Other complications following infusion, transfusion and therapeutic injection

Primary outcomes

1

Description

Serum creatinine level altration

Timepoint

Serum creatinine levels are measured on the first day (day before the procedure) and 48 hours after exposure.

Method of measurement

creatinine test

Secondary outcomes

1

Description

incidence of CIN

Timepoint

48 h post exposure contrast media

Method of measurement

creatinine test

Intervention groups

1

Description

Intervention group: Group II was received Atorvastatin 80mg before coronary procedures (Atorvastatin 80 mg).

Category

Prevention

2

Description

Intervention group: Group III was administered N-acetylcysteine orally as a total dose of 1200 mg before and 600 mg after the coronary procedure (NAC 1800 mg).

Category

Prevention

3

Description

Intervention group: Group IV was prescribed 80 mg of Atorvastatin before the coronary procedure plus N-acetylcysteine as a sum of 1200 mg before and 600 mg after the coronary procedure (Atorvastatin 80 mg plus NAC 1800 mg).

Category

Prevention

4

Description

Control group: Group I was considered as control. They received neither Atorvastatin nor N-acetylcysteine before Coronary procedures.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-ebn Abitaleb hospital

Full name of responsible person

Saeed Keshtkar

Street address

Ali-ebn Abitaleb hospital, Salamat Blvd., Khalij Fars high way

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5570

Email

s.keshtkar20@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Nour Mohammad Bakhshani

Street address

Zahedan University of Medical Sciences, Dr Hesabi square

City

zahedan

Province

Sistan-va-Balouchestan

Postal code

9816737789

Phone

+98 54 3329 5717

Email

parcomss97@gmail.com

Grant name

Grant code / Reference number

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

No

Title of funding source

Research and technology department

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

Zahedan University of Medical Sciences

Full name of responsible person

Saeed Keshtkar

Position

general practitioner

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

Street address

Zahedan University of Medical Sciences, Dr Hesabi square, Zahedan

City

zahedan

Province

Sistan-va-Balouchestan

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9816737789

Phone

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Email

s.keshtkar20@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

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general practitioner

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Phone

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s.keshtkar20@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Saeed Keshtkar

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general practitioner

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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available