Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 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
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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
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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

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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