Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The study of oxygen therapy in preventing contrast nephropathy in patients with acute coronary syndrome undergoing emergent angiography refereed to Resoul Akram hospital in 2018

Protocol summary

Study aim

The study of oxygen therapy in preventing contrast nephropathy in acute coronary syndrome patients undergoing emergent angiography

Design

Clinical trial with control group, with parallel groups, without blinding, randomized, with a sample size of 204 patients

Settings and conduct

All patients were first visited and their creatinine level and arterial blood gas (ABG) were measured in emergency department of Rasoul Akram hospital. The patients were randomly divided into two groups: supplementary oxygen receiving group and the oxygen free group. The first group received 2 to 3 liters of oxygen per minute from the 10 minutes before the start of the procedure until the end of the procedure, and the second group inhaled the oxygen in the room air. ABG were taken prior to receiving oxygen and at the end of the procedure, and all ABGs were sent to the Laboratory of that center. All patients were given a same contrast. The dose of the contrast agent was at least 100 ml and maximum 200 ml. Serum creatinine level was checked for all patients before and 48 hours after the procedure.

Participants/Inclusion and exclusion criteria

Inclusion criteria including: Male or female patients over 35 years old and suspected of coronary artery disease. Non-inclusion criteria included: Arterial oxygen saturation less than 90%, having end stage renal disease, patients undergoing dialysis and candidate for emergency coronary artery bypass surgery

Intervention groups

Intervention group: Supplementary oxygen therapy
Control group: Without supplementary oxygen supply

Main outcome variables

Changes in serum creatinine level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190317043082N1**
Registration date: **2019-04-05, 1398/01/16**
Registration timing: **retrospective**

Last update: **2019-04-05, 1398/01/16**
Update count: **0**

Registration date

2019-04-05, 1398/01/16

Registrant information

Name

Tahereh Zarouk Ahi Mahalleh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8889 6692

Email address

zarouk.t@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-12, 1397/05/21

Expected recruitment end date

2019-01-27, 1397/11/07

Actual recruitment start date

2018-08-12, 1397/05/21

Actual recruitment end date

2019-01-27, 1397/11/07

Trial completion date

2019-01-27, 1397/11/07

Scientific title
The study of oxygen therapy in preventing contrast nephropathy in patients with acute coronary syndrome undergoing emergent angiography refereed to Resoul Akram hospital in 2018

Public title
Effect of oxygen therapy in preventing contrast nephropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Male or female patients over 35 years old Suspected of coronary artery disease
Exclusion criteria:
Arterial oxygen saturation less than 90% Having end stage renal disease Patients undergoing dialysis coronary artery bypass surgery Candidate for emergency coronary artery bypass surgery
Age
From **35 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **204**
Actual sample size reached: **204**
Randomization (investigator's opinion)
Randomized
Randomization description
The random number table and block randomization method were used using http://www.randomizer.org. In this method, eligible patients are divided into blocks of 4 patients. We created random numbers using computer. Based on the determined numerical range to enter individuals in each group, half of the patients in each block assigned to supplementary oxygen and half of them in other group .
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Hazrate Rasoole Akram Hospital,Niayesh St,Satarkhan Av, Tehran
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2016-07-22, 1395/05/01
Ethics committee reference number
IR.IUMS.FMD.REC.1397.238

Health conditions studied

1

Description of health condition studied
Coronary artery disease
ICD-10 code
I24.9
ICD-10 code description
Acute ischemic heart disease, unspecified

Primary outcomes

1

Description
Serum creatinine level
Timepoint
Before the procedure and 48 hours later
Method of measurement
Blood sampling

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: : This group received 2 to 3 liters of oxygen per minute from the 10 minutes before the start of the procedure until the end of the procedure. ABG were taken prior to receiving oxygen and at the end of the procedure. The dose of the contrast agent was at least 100 ml and maximum 200 ml. Serum creatinine level was checked for all patients before and 48 hours after the procedure.
Category
Treatment - Drugs

2

Description
Control group: This group did not receive supplementary oxygen. This group inhaled the oxygen in the room air.

ABG were taken prior to receiving oxygen and at the end of the procedure. The dose of the contrast agent was at least 100 ml and maximum 200 ml. Serum creatinine level was checked for all patients before and 48 hours after the procedure.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Tahereh Zarouk Ahi Mahalleh

Street address

Hazrate Rasoole Akram Hospital,Niayesh St,Satarkhan Av, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8744 3210

Email

zarouk.t@ums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Shahin Akhoundzadeh

Street address

Hazrate Rasoole Akram Hospital,Niayesh St,Satarkhan Av, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

research@ums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Tehran University of Medical Sciences

Full name of responsible person

Tahereh Zarouk Ahi Mahalleh

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Number 21, Dameshgh St., Vali-e Asr Ave., Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8889 6692

Fax

Email

zarouk.t@ums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

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Tahereh Zarouk Ahi Mahalleh

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Person responsible for updating data

Contact

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Tehran University of Medical Sciences

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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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is 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
All potential data is shareable after being unidentifiable

When the data will become available and for how long
Up to 2019-09-01

To whom data/document is available
All university researchers

Under which criteria data/document could be used
Email

From where data/document is obtainable
Email

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

Comments