

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

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

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+98 21 8889 6692

Email address

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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 referred 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

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

Iran University of Medical Sciences

Full name of responsible person

Shahin Akhoundzadeh

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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

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

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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

Email

Comments