Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Comparison of the effect of oxygen and placebo on clinical outcomes in patients with non ST elevation acute coronary syndrome

Protocol summary

Summary

This is a triple-blind clinical trial that will be performed to evaluate the effects of supplemental oxygen on some clinical outcomes (consumption of analgesics, cardiac dysrhythmias, recurrence of chest pain and readmission) in patients with non ST elevation acute coronary syndrome in Bushehr Heart Center. Seventy patients with non ST-segment elevation acute coronary syndromes who have arterial oxygen saturation greater than 90 percent will be selected with purposive sampling and will be randomly divided into intervention (supplemental oxygen) and placebo (room air) groups. Patients in the intervention group will receive 4-6 liters per minute of oxygen by nasal cannula for up to 6 hours after admission. Patients in the control group will receive the same amount of air with the same way. The incidence of cardiac dysrhythmias in the first 24 hours, the frequency of chest pain and analgesic consumption in second day, and readmission in the first 30 days will be checked.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081118768N1**
Registration date: **2014-11-24, 1393/09/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-11-24, 1393/09/03

Registrant information

Name

Fatemeh Heidari

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oxygen and placebo on clinical outcomes in patients with non ST elevation acute coronary syndrome

Public title

Comparison of the effect of oxygen and placebo in treatment of non ST elevation acute coronary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18-84 years; diagnosed with acute coronary syndrome with non ST segment elevation according to Branvald criteria; no clinical evidence of heart failure; no chronic lung disease or other respiratory problems; lack of cardiac arrest or cardiogenic shock before entering the hospital; oxygen saturation above 90% on admission; absence of

congenital heart disease. Exclusion criteria: Need for inotropic support; having ST elevation acute myocardial infarction; oxygen saturation less than 90% during hospitalization; emergency coronary angioplasty or emergency coronary artery bypass during hospitalization; death.

Age
From **18 years** old to **84 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Bushehr University of Medical Sciences

Street address
Bushehr University of Medical Sciences, Salman Farsi street, Bushehr, Bushehr, Iran

City
Bushehr

Postal code
7514633341

Approval date
2014-08-11, 1393/05/20

Ethics committee reference number
B-93-16-7

Health conditions studied

1

Description of health condition studied
Ischaemic heart diseases

ICD-10 code
I20.0, I21

ICD-10 code description
آنژین ناپایدار، انفارکتوس حاد میوکارد ساب اندوکارد

Primary outcomes

1

Description
Cardiac dysrhythmias

Timepoint
Continues over 24 hours

Method of measurement
Cardiac monitoring device

2

Description
Chest pain

Timepoint
24 - 28 - 32 - 36 - 40 - 44 - 48 hours

Method of measurement
check list, visual analogue scale

3

Description
The amount of narcotic analgesic

Timepoint
48 hours

Method of measurement
check list

Secondary outcomes

1

Description
Readmission due to cardiac problems

Timepoint
End of weeks 1- 2- 3- 4

Method of measurement
The phone call

2

Description
Visit due to cardiac problems

Timepoint
End of weeks 1- 2- 3- 4

Method of measurement
The phone call

Intervention groups

1

Description
Intervention group: at 6 hours after arriving at the hospital, oxygen will be given at a rate of 4 to 6 liters per minute by nasal cannula.

Category
Treatment - Drugs

2

Description
Control group: at 6 hours after arriving at the hospital, room air will be given at a rate of 4 to 6 liters per minute by nasal cannula.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bushehr Heart Center
Full name of responsible person
Dr Daruosh Iranpur
Street address
Bushehr Heart Center, Moallem street, Bushehr, Bushehr, Iran
City
Bushehr

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy of Arak University of Medical Sciences
Full name of responsible person
Mr.Babaie
Street address
University of Medical Sciences, Sardasht, Arak, Markazi, Iran
City
Arak
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy of Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty