

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 86 3417 3501

###### Email address

f.heidari@arakmu.ac.ir

###### 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

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

Fatemeh Heidari

#### Position

Bachelor of nursing

#### Other areas of specialty/work

#### Street address

Arak University of Medical Sciences, Sardasht, Arak, Markazi, Iran

#### City

Arak

#### Postal code

3848176941

#### Phone

+98 77 1252 7971

#### Fax

+98 86 3417 3639

#### Email

f.heidari@arakmu.ac.ir/mahboobeh63n@yahoo.com

#### Web page address

www.ararkmu.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

Kobra Rahzani

#### Position

PHD of nursing

#### Other areas of specialty/work

#### Street address

Arak University of Medical Sciences, Sardasht, Arak, Markazi, Iran

#### City

Arak

#### Postal code

3848176941

#### Phone

+98 86 3417 3503

#### Fax

+98 86 3417 3639

#### Email

k.razani@arakmu.ac.ir

#### Web page address

www.arakmu.ac.ir

## Person responsible for updating data

### Contact

#### Name of organization / entity

Arak University of Medical Sciences

#### Full name of responsible person

Fateme Heidari

#### Position

Bachelor of Nursing

#### Other areas of specialty/work

#### Street address

Arak University of Medical Sciences, Sardasht, Arak, Markazi, Iran

**City**

Arak

**Postal code**

3848176941

**Phone**

+98 86 3417 3505

**Fax**

+98 86 3417 3639

**Email**

f.heidari@arakmu.ac.ir

**Web page address**

www.arakmu.ac.ir

**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*