

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### The effect of oxygen therapy with nasal cannula and Venturi mask on SPO2 and arterial blood gases after extubation in patients undergoing CABG

#### Protocol summary

##### Study aim

Determination of the effect of oxygen therapy with nasal catheter and ventricular mask, after removing the tracheal tube, on the saturation of hemoglobin saturated with oxygen and arterial blood gas in patients undergoing coronary artery bypass graft surgery

##### Design

Randomized random sampling from patients with inclusion criteria was performed using random allocation software. After selecting the study samples, they were assigned to two groups using the random allocation software. The number of samples was considered to be 120 patients in two groups of mask and nasal catheter.

##### Settings and conduct

Performing oxygen therapy with nasal catheter and mask for half an hour after removing the tracheal tube and recording vital signs and data on arterial blood gases in patients who had entered the study, who performed in the intensive care unit of the heart of Afshar, Yazd Became.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria Having ages 40 to 70 years, patients undergoing coronary artery bypass graft surgery, facial skin and ear and nose, and absence of chronic obstructive pulmonary disease, Ejection Fraction > 40% before surgery Exit criteria Lack of successful weaning, lack of self-breathing after Extract the tracheal tube, abnormal level of consciousness (Glasgow Coma Scale <15), Instability of the patient's vital signs (more than 500 cc discharge in 6 hours on the first day)

##### Intervention groups

mask group and nose catheter group

##### Main outcome variables

Oxygen therapy, arterial blood gases and vital signs

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170701034831N2**

Registration date: **2018-09-03, 1397/06/12**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-09-03, 1397/06/12**

Update count: **0**

##### Registration date

2018-09-03, 1397/06/12

##### Registrant information

##### Name

Hamide Setoodenia karani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3824 1751

##### Email address

h.setoodenia@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Sadoughi University of Medical Sciences Yazd

##### Expected recruitment start date

2018-08-23, 1397/06/01

##### Expected recruitment end date

2018-11-22, 1397/09/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The effect of oxygen therapy with nasal cannula and Venturi mask on SPO2 and arterial blood gases after extubation in patients undergoing CABG

### Public title

The effect of oxygen therapy with nasal cannula and Venturi mask on arterial blood gases

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age 40 to 70 years Patients undergoing coronary artery bypass graft surgery Healthy facial skin and ears and nose Lack of chronic obstructive pulmonary disease Ejection Fraction > 40% before surgery

#### Exclusion criteria:

Unsuccessful weaning of ventilator device Not having spontaneous breath after removing the tube trachea Glasgow Coma Scale < 15 Vital Signs unstable

### Age

From **40 years** old to **70 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

- Care provider
- Investigator
- Data analyser

### Sample size

Target sample size: **120**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomized random sampling from patients with inclusion criteria was performed using random allocation software. After selecting the study samples, they were assigned to two groups using the random allocation software.

### Blinding (investigator's opinion)

Single blinded

### Blinding description

The trained nurse responsible for collecting samples is due to the same type of care in relation to all patients.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Yazd University of Medical Sciences

##### Street address

Bahonar Square, Shahid Sadoughi Blvd, Bahonar Square.

##### City

Yazd

##### Province

Yazd

##### Postal code

8917182995

#### Approval date

2017-10-09, 1396/07/17

#### Ethics committee reference number

ir.ssu.rec.1396.79

## Health conditions studied

### 1

#### Description of health condition studied

Signs and arterial blood gases after extubation

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Arterial blood gases and vital signs

#### Timepoint

Immediately before and after caffeine and time after intercourse

#### Method of measurement

Arterial blood sample, monitoring of vital signs, vas

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Oxygen therapy by two methods of nasal cannula and Vancouver massage at a rate of six liters per minute for half an hour after extubation of the trachea

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Afshar hospital

**Full name of responsible person**

Hamide Setoodenia Karani

**Street address**

Faculty of Nursing., Infertility Research Center., Bouali Ave., timsar Fallah Avenue., Safaiyeh

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**Email**

hamide.setoodenia@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Hamide setoodenia

**Street address**

Sadoughi Boulevard., Bahonar Square

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yazd

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**Postal code**

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**Email**

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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**

Yazd 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Hamide Setoodenia Karani

**Position**

Nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

Infertility Research Center., Timsar Fallahi Avenue., Bouali Ave., Safaye

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

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Hamide Setoodenia karani

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Nurse

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## Person responsible for updating data

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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