

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jul 2026

### The effect of oxygen therapy in the basis of blood oxygen saturationlevels monitoring on the heart tissue perfusion in patients with acutemyocardial infarction Hospitalized in the cardiac care unit

#### Protocol summary

##### Study aim

Determine the effect of oxygen therapy based on monitoring of arterial oxygen saturation on the status of heart tissue in blood Patients with acute myocardial infarction

##### Design

This is a clinical trial conducted in parallel in two groups of test and control.

##### Settings and conduct

This study was performed on patients with acute myocardial infarction admitted to the Cardiac Care Unit of Ziaie Ardakan Hospital.

##### Participants/Inclusion and exclusion criteria

Entry requirements: Acute myocardial infarction with elevated ST segment; People over 18 years of age who have had more than 12 hours of onset of symptoms of ischemia; No respiratory disease. Conditions of non-arrival: previous infarction; cardiogenic shock; patient transmission from other departments or hospitals.

##### Intervention groups

patients will be divided into two groups according to available sampling and simple random assignment in lottery mode. control group patients, after admission recives oxygen with mask or nasal catheter Based on routine. But ,the test group, percentage of oxygen saturation will be monitored and if Less than 90%, Oxygen Therapy will be performed with a simple face mask or nasal catheter.

##### Main outcome variables

If the results of the study indicate that oxygen can be improved by monitoring SPO2 Heart tissue hemorrhage in patients with STEMI will be used for clinical use.

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20180321039134N1**

Registration date: **2018-10-22, 1397/07/30**

Registration timing: **retrospective**

Last update: **2018-10-22, 1397/07/30**

Update count: **0**

#### Registration date

2018-10-22, 1397/07/30

#### Registrant information

##### Name

Fatemeh Poorahmadiéh ardakan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3223 7096

##### Email address

F.POORAHMADIEH@SSU.AC.IR

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2018-01-21, 1396/11/01

#### Expected recruitment end date

2018-08-22, 1397/05/31

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of oxygen therapy in the basis of blood oxygen saturationlevels monitoring on the heart tissue perfusion

in patients with acutemyocardial infarction Hospitalized  
in the cardiac care unit

**Public title**

Effect of Oxygen on Myocardial Infarction

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

STEMI Perad over 15 years of age, more than 12 hours  
after the onset of symptoms of an ischemic attack  
Absence of respiratory illness

**Exclusion criteria:**

Previous infarction Cardiogenic shock Transferring the  
patient from other departments or hospitals Cardiac  
arrest at the time of admission

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **64**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Eligible patients will be divided into two groups according  
to available sampling and simple random assignment in  
lottery mode.

**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 yazd University of Medical  
Sciences

**Street address**

Bahonar Square, Central Building of University of  
Medical Sciences Yazd

**City**

yazd

**Province**

Yazd

**Postal code**

1558738816

**Approval date**

2018-01-10, 1396/10/20

**Ethics committee reference number**

ir.ssu.res.1396.168

**Health conditions studied****1****Description of health condition studied**

Acute myocardial infarction

**ICD-10 code**

I00-I99

**ICD-10 code description**

Diseases of the circulatory system

**Primary outcomes****1****Description**

Measuring Troponin I

**Timepoint**

Come to study and finish 24 hours and 48 hours after  
entering the study

**Method of measurement**

I\_chroma device

**Secondary outcomes****1****Description**

ST segment changes

**Timepoint**

Admission; End of the first 24 hours; End 48 hours.

**Method of measurement**

ECG

**2****Description**

Measurement of creatinine phosphokinase enzyme

**Timepoint**

At the patient's admission, 12hours later and 24 hours  
after the initial admission

**Method of measurement**

BT6400 device

**Intervention groups****1****Description**

Intervention group: Intervention group: Patients  
measured by pulse oximetry after the nurse's  
acceptance of blood oxygen levels. When oxygen  
saturation in patients is less than 90%, oxygen therapy  
with a face mask or nasal catheter according to patient  
selection, by A researcher or researcher assistant will  
start for the patient until the oxygen arterial blood level

reaches 90% or more.

**Category**

Prevention

**2**

**Description**

Control group: Control group: Patients in the control group are those who, after being admitted by the shift nurse, although all the patients undergo cardiac monitoring and controlled by pulse oximetry, control their arterial blood oxygen saturation, they initiate oxygen therapy with a mask or nasal catheter While there may not be a drop in oxygen levels, the oxygen content is between 5 and 7liters per minute.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Ziaei Ardekan Hospital

**Full name of responsible person**

Naiire Salmani

**Street address**

Ziaie Hospital, Moallem Blvd

**City**

Ardekan

**Province**

Yazd

**Postal code**

8916877441

**Phone**

+98 35 3824 1751

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+98 35 3824 9705

**Email**

n.salmani@ssu.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Deputy Research and Technology

**Street address**

Ziaee Hospital, Teacher Blvd, Azadi Square, Ardakan

**City**

Ardakan

**Province**

Yazd

**Postal code**

8951859931

**Phone**

+98 35 3152 3224

**Email**

poorahmadieh@gmail.com

**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**

Fatemeh Pourahmadieh Ardakan

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

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**Phone**

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**Email**

poorahmadieh@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Naiire Salmani

**Position**

Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

TimSarFallahi Avenue, Bou-Ali St, in front of Infertility  
Research Center, yazd

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Personal information is confidential in the study.

**Study Protocol**

No - There is not 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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

After the study is completed, the results will be available for use at the clinic and the use of other colleagues.

**When the data will become available and for how long**

3 months after receiving results

**To whom data/document is available**

Faculty Members of Yazd Nursing College

**Under which criteria data/document could be used**

To compare with other studies.

**From where data/document is obtainable**

poorahmadieh@gmail.com

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

Expressing what information it wants to use and providing a valid degree from a place of study or work.

**Comments**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Naiire Salmani

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

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