

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

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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

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8951859931

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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

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Ziaee Hospital, Teacher Blvd, Azadi Square, Ardakan, Yazd

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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

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TimSarFallahi Avenue, Bou-Ali St, in front of Infertility
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Person responsible for updating data

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Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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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