

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of The Effect of Taking Oxygen with Not Taking Oxygen in the Prognosis of Patients with Acute Myocardial Infarction

Protocol summary

Study aim

The main aim is to compare the effect of oxygen with non-oxygen on the prognosis of patients with acute myocardial infarction.

Design

In this project, a randomized trial will be performed based on the evaluation of supplemental oxygen versus air in patients with AMI who were not initially hypoxic. This random sampling will be done from a computer catalogue using an online random model. Oxygen saturation is recorded at the beginning and end of treatment.

Settings and conduct

The study areas are all Zahedan educational hospitals. The study includes patients aged 30 years or older who came to the emergency or cardiac intensive care by ambulance or by themselves. During this research, evaluations are provided to the research team without the information of the study group. Descriptive statistics are used to describe the data, standard deviation, frequency and percentage. The comparison and difference between the results of oxygen therapy in patients with myocardial infarction are determined by chi-square test. The T-test is used to compare the average time of patients' hospitalizations. The p-value (>0.05) is considered to show the statistical difference. All analyses are performed with SPSS software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Patients who have symptoms suggestive of MI - ECG changes with elevated cardiac troponin - Oxygen saturation of 90% or higher on pulse oximetry Exclusion criteria: - Patients who have continuous oxygen therapy - Patients who have suffered cardiac arrest prior to inclusion - If supplemental oxygen therapy is started before evaluation for inclusion for less than 20 minutes

Intervention groups

Patients are randomly selected to receive oxygen through an oral mask (6 litres per minute for the next 6

to 12 hours) or room air.

Main outcome variables

Effect of supplemental oxygen versus air in patients with AMI

General information

Reason for update

Acronym

Electro Cardio Gram=ECG/Acute Myocardial Infarction=AMI

IRCT registration information

IRCT registration number: **IRCT20200901048576N1**

Registration date: **2021-03-15, 1399/12/25**

Registration timing: **retrospective**

Last update: **2021-03-15, 1399/12/25**

Update count: **0**

Registration date

2021-03-15, 1399/12/25

Registrant information

Name

Mahsa Zeiaesaeidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 4304

Email address

mahsa.zsd@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-25, 1398/01/05

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of The Effect of Taking Oxygen with Not Taking Oxygen in the Prognosis of Patients with Acute Myocardial Infarction

Public title

The Effect of Oxygen Therapy in Acute Myocardial Infarction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who present to emergency department Zahedan University Hospital Patients who have symptoms suggestive of MI ECG changes with elevated cardiac troponin Oxygen saturation of 90% or higher on pulse oximetry Patients who have Iranian nationality Patients who orally are agreed to participate and have signed consent forms

Exclusion criteria:

Patients who have continuous oxygen therapy Patients who have suffered cardiac arrest prior to inclusion If supplemental oxygen therapy is started before evaluation for inclusion for less than 20 minutes, new evaluation can take place after discontinuation of oxygen delivery and ten minutes of wash-out .

Age

From **30 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this method, based on the sample size, we will prepare a number of envelopes whose contents are not known at all, and then on the cards, random sequences that have been generated online through the randomization website for random allocation. We put them in envelopes. Now the concealment must be done on the method used to execute the random sequence on the participants. So that before the assignment of each person, his / her assigned group is not known. Without this, there is a possibility of disclosing the sequences, which will weaken the research. On the other hand, it can lead to the elimination of certain patients based on their prognosis, or patients with better conditions enter the intervention group and patients with worse conditions. Be the control group and cause the selection bias in the study as a whole. Therefore, it is necessary to

make a decision to participate or reject the study from the beginning and fill in the informed consent forms and then the participants are randomly assigned to each group. In the implementation of the random allocation process, what is important is the person who performs this process, who should not be in other stages of this research and should be separate from other researchers in order to reduce possible bias.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

NA

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Zahedan University of Medical Sciences

Street address

ZAUMS Main campus, Zahedan, Sistan and Baluchestan, Iran

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Zahedan

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9816743463

Approval date

2019-02-04, 1397/11/15

Ethics committee reference number

IR.ZAUMS.REC.1397.430

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

Acute myocardial infarction

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The mortality rate of people who were diagnosed by MI and have been treated with oxygen

Timepoint

During one and three months after oxygen therapy

Method of measurement

Number of patients who died or survived during follow-up

2

Description

The mortality rate in people with acute MI without receiving oxygen

Timepoint

During one and three months after oxygen therapy

Method of measurement

Number of patients who died or survived during follow-up

3

Description

The rate of re-hospitalization of people due to acute MI with receiving oxygen

Timepoint

During one and three months after oxygen therapy

Method of measurement

Re-hospitalization (measured by the number of patients who have been re-admitted for three months)

4

Description

The rate of re-hospitalization of people due to acute MI without receiving oxygen

Timepoint

During one and three months after oxygen therapy

Method of measurement

Re-hospitalization (measured by the number of patients who have been re-admitted for three months)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 25 people are randomly selected to receive oxygen through an oral mask at 6 litres per minute during the 6 to 12 hours of emergency hospitalization.

Category

N/A

2

Description

Control group: A total of 25 people are selected to receive oxygen existing at the room without any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Hospital/Imam Ali Research Hospital

Full name of responsible person

Mahsa Zeiaesaeidi

Street address

Khatam Hospital, Jame Jam Blvd, Zahedan, Sistan and Baluchestan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

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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

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Mahsa Zeiaesaeidi

Position

Physicians assistant

Latest degree

Medical doctor

Other areas of specialty/work

Emergency Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

No - There is not 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

Title and more details about the data/document

All types of data (related to changes of oxygen therapy in acute myocardial infarction) will be published as anonymous for each planned publication.

When the data will become available and for how long

The data will be available six months after publishing the first draft of data analysis and results in national and international journals and conferences.

To whom data/document is available

All sorts of findings and data analyses for future academic and industrial researchers.

Under which criteria data/document could be used

It may be necessary to use these research findings to write-up future research on this topic. Therefore, by maintaining the anonymity of the patients, the findings are available for other researchers.

From where data/document is obtainable

They should be in touch with Mahsa Zeiasaeidi as chief investigator of this research via mahsa.zsd@zaums.ac.ir.

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

There is a need to contact Mahsa Zeiasaeidi (chief investigator of this research) via email. She will share all available data to the inquirer within less than six months.

Comments

