# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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 themself. 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 Infraction=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

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**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 Infraction
**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
**City**
Zahedan
**Province**
Sistan-va-Balouchestan
**Postal code**
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**
Prof. Nourmohammad Bakhshani
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+98 54 3337 2116
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zaums.research@gmail.com
**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 scientific inquiries

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## Person responsible for updating data

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Physicians assistant

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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**