

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Determination of the Role of Oxygen in Suspected Acute Myocardial Infarction by Biomarkers

#### Protocol summary

##### Study aim

Determination of the Role of Oxygen in Suspected Acute Myocardial Infarction by Biomarkers

##### Design

This study is a clinical trial with control group and double blind randomized parallel groups in which 352 eligible patients will be randomly assigned to intervention and control groups

##### Settings and conduct

Patients with ACS referred to Golestan and Imam Khomeini hospitals will be included in the study if eligible

##### Participants/Inclusion and exclusion criteria

Patients with acute myocardial infarction

##### Intervention groups

First group: receive O<sub>2</sub> as interventional medication  
Second group: receive environmental air as placebo

##### Main outcome variables

Cardiac bio-markers (in our study troponin), as the most important indicator of our study, will be measured at 2 locations

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190922044850N1**

Registration date: **2019-10-10, 1398/07/18**

Registration timing: **retrospective**

Last update: **2019-10-10, 1398/07/18**

Update count: **0**

##### Registration date

2019-10-10, 1398/07/18

##### Registrant information

##### Name

Ehsan Kiani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3227 5806

##### Email address

dr.ehsan.kiani@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-21, 1398/01/01

##### Expected recruitment end date

2019-06-21, 1398/03/31

##### Actual recruitment start date

2019-03-21, 1398/01/01

##### Actual recruitment end date

2019-06-21, 1398/03/31

##### Trial completion date

2019-08-23, 1398/06/01

##### Scientific title

Determination of the Role of Oxygen in Suspected Acute Myocardial Infarction by Biomarkers

##### Public title

the Role of Oxygen in Suspected Acute Myocardial Infarction

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

Presence of ACS (Acute coronary syndrome) in patients  
Lack of O<sub>2</sub> intake in other centers  
Lack of history of Heart Failure  
Lack of history of COPD (Chronic obstructive pulmonary disease)  
Lack of history of respiratory diseases

##### Exclusion criteria:

Need for Inotropic agents  
So<sub>2</sub> less than 90%  
Dissatisfaction  
Admission less than 6 hours in hospital

Unstable vital signs

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**  
Target sample size: **350**  
Actual sample size reached: **352**

**Randomization (investigator's opinion)**  
Not randomized

**Randomization description**

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
According to the blinded study, neither the researcher nor the patients would know the type of gas received, the study was double-blind.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Ethics committee of AJUMS

**Street address**

No 10, 20 Eghbal Ave, Kourosh, Ahwaz, Khuzestan, Iran

**City**

Ahwaz

**Province**

Khuzestan

**Postal code**

46416164

**Approval date**

2018-09-17, 1397/06/26

**Ethics committee reference number**

IR.AJUMS.REC.1397.397

## Health conditions studied

### 1

Description of health condition studied

Determination of the Role of Oxygen in Suspected Acute Myocardial Infarction by Biomarkers

**ICD-10 code**

I21.9

**ICD-10 code description**

Acute myocardial infarction, unspecified

## Primary outcomes

### 1

**Description**

Troponin

**Timepoint**

On arrival and 4-6 hours after the patients arrive at the emergency department

**Method of measurement**

Blood sample

### 2

**Description**

LVEF(Left Ventricular Ejection Fraction)

**Timepoint**

On arrival and 4-6 hours after the patients arrive at the emergency department

**Method of measurement**

Eco cardiography

### 3

**Description**

arrhythmia

**Timepoint**

On arrival and 4-6 hours after the patients arrive at the emergency department

**Method of measurement**

ECG (Electrocardiogram)

### 4

**Description**

heart pain

**Timepoint**

On arrival and 4-6 hours after the patients arrive at the emergency department

**Method of measurement**

Asking the patient

### 5

**Description**

Opioid drugs

**Timepoint**

On arrival and 4-6 hours after the patients arrive at the emergency department

**Method of measurement**

Based on the mg prescribed

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Patients with ACS referred to Golestan and Imam Khomeini teaching hospitals of Ahwaz with inclusion criteria who will be given oxygen by nasal method for 4-6 hours at 4-6 liters / min and According to the blinding done, neither the researcher nor the patients will know the type of gas received.

#### Category

Diagnosis

### 2

#### Description

Control group: control group:Patients with ACS referred to Golestan and Imam Khomeini teaching hospitals of Ahwaz with inclusion criteria who will be given Room air by nasal method for 4-6 hours at 4-6 liters / min and According to the blinding done, neither the researcher nor the patients will know the type of gas received.

#### Category

Diagnosis

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hospital golestan university

##### Full name of responsible person

Ehsan Kiani

##### Street address

Golestan Educational and Medical Center, Farvardin Street, Golestan, Ahwaz

##### City

Ahwaz

##### Province

Khuzestan

##### Postal code

33118-61357

##### Phone

+98 61 3374 3014

##### Email

golestanhospital@ajums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Imam Khomeini Hospital of Ahwaz

##### Full name of responsible person

Ehsan Kiani

##### Street address

mam Khomein hospital, Azadegan Street, Ahwaz

##### City

Ahwaz

##### Province

Khuzestan

##### Postal code

6193673111

##### Phone

+98 61 3222 2922

##### Email

himam@ajums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahwaz University of Medical Sciences

##### Full name of responsible person

Mohammad Badvi

##### Street address

No 10, 20 Eghbal Ave, Kourosh, Ahwaz, khuzestan, Iran

##### City

Ahwaz

##### Province

Khuzestan

##### Postal code

46416164

##### Phone

+98 61 3336 2414

##### Email

info@ajums.ac.ir

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Ahwaz 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

Ahwaz University of Medical Sciences

##### Full name of responsible person

Ehsan Kiani

##### Position

resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Cardiology

##### Street address

Floor 2, Unit 6, No. 10, Building Complex, 20 Eghbal Ave, Kourosh, Ahwaz

**City**

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**Province**

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**Postal code**

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**Phone**

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**Email**

Dr.ehsan.kiani@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Ahwaz University of Medical Sciences

**Full name of responsible person**

Ehsan Kiani

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Ahwaz University of Medical Sciences

**Full name of responsible person**

Ehsan Kiani

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Email**

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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