

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of diaphragmatic breathing on chest pain, anxiety and physiologic parameters in patients with acute coronary syndrome in the emergency department

#### Protocol summary

##### Study aim

Effect of diaphragmatic breathing on chest pain, anxiety and physiologic parameters in patients with acute coronary syndrome in the emergency department

##### Design

A clinical trial with a parallel group, with randomized block design, With a sample size of 60 patients

##### Settings and conduct

To perform the study, research samples were assigned to the following groups randomly: The first group: performing of diaphragmatic breathing for 10 minutes. The second group: routine actions. The intensity of chest pain, anxiety and the vital signs of systolic pressure, diastolic pressure, pulse, and oxygen saturation will be measured in before and after the intervention/routine actions in the two groups.

##### Participants/Inclusion and exclusion criteria

Ability to communicate; Addiction; Diabetes diseases

##### Intervention groups

Intervention group: Perform diaphragmatic breathing for 10 minutes, first raising the patient's head up to 30 degrees, and asking the patient to place his hands preferably on the abdomen and then first take a gentle breath from the nose. The patient is requested to focus on the abdomen while breathing deeply, and to pay attention to the extent of the abdomen to a maximum extent so that its elevation can be seen or felt by the hands it is placed on the abdomen. Then, after a full tail, the exertion is slowly performed. Control group: Routine action is done.

##### Main outcome variables

Chest pain severity; anxiety; vital signs

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20101108005134N12**

Registration date: **2019-01-09, 1397/10/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-01-09, 1397/10/19**

Update count: **0**

#### Registration date

2019-01-09, 1397/10/19

#### Registrant information

##### Name

Ali Fakhr-Movahedi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 23 3365 4192

##### Email address

Alimovi49@semums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-12-22, 1397/10/01

#### Expected recruitment end date

2020-03-21, 1399/01/02

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of diaphragmatic breathing on chest pain, anxiety and physiologic parameters in patients with

acute coronary syndrome in the emergency department

## Public title

Effect of diaphragmatic breathing pain severity, anxiety and physiologic parameters

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Ability to communicate The first time of getting acute coronary syndrome Normal respiration pattern in patient

### Exclusion criteria:

Addiction Diabetes disease Injury to chest and abdomen Occurring crisis condition Alteration in patient status

## Age

From **40 years** old to **80 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The research sample assigned to the groups of the study by permuted blocks randomization. Also, blocking be used within gender and age strata.

## 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 Semnan University of Medical Sciences

##### Street address

Research and technology deputy, Semnan University of Medical Sciences, Basij Blvd

##### City

Semnan

##### Province

Semnan

##### Postal code

35198-99951

#### Approval date

2018-11-20, 1397/08/29

## Ethics committee reference number

IR.SEMUMS.REC.1397.194

## Health conditions studied

### 1

#### Description of health condition studied

Acute ischemic heart disease

#### ICD-10 code

I24.9

#### ICD-10 code description

Acute ischemic heart disease, unspecified

## Primary outcomes

### 1

#### Description

Chest pain severity

#### Timepoint

Before and immediately after intervention

#### Method of measurement

The pain numerical rating scale

### 2

#### Description

Anxiety

#### Timepoint

Before and after intervention

#### Method of measurement

7 item anxiety Spielberger scale

### 3

#### Description

Blood pressure

#### Timepoint

Before and after intervention

#### Method of measurement

Aneroid sphygmomanometer

### 4

#### Description

Pulse

#### Timepoint

Before and after intervention

#### Method of measurement

Pulse oximeter

### 5

#### Description

O2 saturation

#### Timepoint

Before and after intervention

#### Method of measurement

Pulse oximeter

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Perform diaphragmatic breathing for 10 minutes, first raising the patient's head up to 30 degrees, and asking the patient to place his hands preferably on the abdomen and then first take a gentle breath from the nose. The patient is requested to focus on the abdomen while breathing deeply, and to pay attention to the extent of the abdomen to a maximum extent so that its elevation can be seen or felt by the hands it is placed on the abdomen. Then, after a full tail, the exertion is slowly performed.

### Category

Treatment - Other

2

### Description

Control group: Routine action is done.

### Category

N/A

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Army hospital 502

#### Full name of responsible person

Dr. Masoud Memarian

#### Street address

Corner of Bahar St., Taleghani Ave.

#### City

Tehran

#### Province

Tehran

#### Postal code

15717

#### Phone

+98 21 8882 8001

#### Email

info@502hospital.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Semnan University of Medical Sciences

#### Full name of responsible person

Dr. Parviz Kokhaei

#### Street address

Research and technology deputy, Semnan University

بلوار بسیج؛ دانشگاه علوم پزشکی سمنان؛ معاونت تحقیقات و فناوری  
of Medical Sciences, Basij Blvd.

#### City

Semnan

#### Province

Semnan

#### Postal code

35198-99951

#### Phone

+98 23 3344 1022

#### Email

p\_kokha@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Semnan 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

Semnan University of Medical Sciences

#### Full name of responsible person

Dr. Ali Fakhr-Movahedi

#### Position

Associate professor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Nursery

#### Street address

Nursing School, Semnan University of Medical Sciences, 5th km Damghan road

#### City

Semnan

#### Province

Semnan

#### Postal code

35198-99951

#### Phone

+98 23 3365 4192

#### Email

Alimovi@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Semnan University of Medical Sciences

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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**

No more information

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

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

1. The study protocol 2. The results of the study

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

After termination of the study

**To whom data/document is available**

1. Faculty members 2. The clinical nurses 3. The medical and nursing students

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

Access to data or documentation is subject to the following conditions: 1- Use in Future Studies References 2- The future studies

**From where data/document is obtainable**

Please contact Ali Fakhr-Movahedi Email: alimovi@yahoo.com

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

After emailing Ali Fakhrmohahdi, email will be answered as soon as possible.

**Comments**