

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Effect of deep and slow breathing on consequences of pain during arterial sheath removal in patients undergoing percutaneous coronary intervention

#### Protocol summary

##### Summary

Patients who underwent coronary angioplasty placed first with a purposive sample included in the study and randomly placed in two groups. Before removing the sheet, deep breathing techniques are taught to the patient and asked for action to inhale and exhale ratio of 4: 6 do. This face to face training to maintain the direction of the tail to the expiration of counting used. All sheet for 5 minutes after starting slow, deep breathing and took out the tail end. Patients in the control group in the usual way and without the use of deep breathing and slow the sheet out. To collect data, a questionnaire on demographic information (age, sex, marital status, occupation, education level, height and weight, underlying diseases (diabetes, hypertension) is used. The pain and hemodynamic symptoms such as systolic blood pressure and diastolic, heart rate and respiratory rate), to remove the sheet, immediately, 5, 10, 15, and 20 minutes after removal of the arterial sheath can be measured. To measure the intensity of the pain visual analogue scale of pain. Clean exit the vascular complications (bleeding, hematoma , pseudoaneurysm ) immediately, 4 and 24 hours after the check homeostasis and in case of any complications will be recorded.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015050622120N1**

Registration date: **2015-11-03, 1394/08/12**

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

Last update:

Update count: **0**

##### Registration date

2015-11-03, 1394/08/12

#### Registrant information

##### Name

Zahra Yousefi

##### Name of organization / entity

Arak University Of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8800 2120

##### Email address

z.yusefi@arakmu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Arak University of Medical Sciences

#### Expected recruitment start date

2015-10-23, 1394/08/01

#### Expected recruitment end date

2016-01-21, 1394/11/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of deep and slow breathing on consequences of pain during arterial sheath removal in patients undergoing percutaneous coronary intervention

#### Public title

Effect of deep and slow breathing on consequences of pain during arterial sheath removal in patients undergoing percutaneous coronary intervention

#### Purpose

Supportive

#### Inclusion/Exclusion criteria

Patients in the study are that have these criteria: • For the first time undergoing coronary angioplasty, as well. • Have the ability to learn. • Has a mental disorder is not known, according to their relatives. • Fluency in Farsi and is able to communicate. • To participate in the study have written consent. • Systolic blood pressure is less than 130 mmhg. • any shortness of breath and breathing difficulties are clear. • The absence of pain and complication of vascular puncture to remove the sheet. Patients who have the following conditions shall be excluded: • Housing has received for any reason. • Experience shortness of breath, irregular heart disease, congestive heart failure or heart attack is. • Experiencing cardiac arrest is from respiratory or loss of consciousness. • Be deterred from continuing to study. • Fatal or transfer him to the operating room for emergency surgery any.

**Age**

No age limit

**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****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**

Arak University of Medical Sciences

**Street address**

Arak University of Medical Sciences, Sardasht

**City**

Arak

**Postal code****Approval date**

2015-04-20, 1394/01/31

**Ethics committee reference number**

IR.ARAKMU.REC.1394.1

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

Patients undergoing coronary angioplasty

**ICD-10 code**

Z95.5

**ICD-10 code description**

Status following coronary angioplasty NOS

**Primary outcomes****1****Description**

Pain

**Timepoint**

Before the intervention, immediately after the intervention, 10 and 20 minutes after intervention

**Method of measurement**

Pain visual scale

**Secondary outcomes****1****Description**

Blood pressure

**Timepoint**

Before the intervention, immediately, 5,10,15,20 minutes later

**Method of measurement**

Digital Sphygmomanometer

**2****Description**

Pulse Rate

**Timepoint**

Before the intervention, immediately, 5,10,15,20 minutes later

**Method of measurement**

Cardiac monitoring

**3****Description**

Respiratory rate

**Timepoint**

Before the intervention, immediately, 5,10,15,20 minutes later

**Method of measurement**

Respiration monitoring

**4****Description**

Bleeding

**Timepoint**

Immediately after the homeostasis, 4 and 24 hours later

**Method of measurement**

Observation

## 5

### Description

Hematoma

### Timepoint

Immediately after the homeostasis, 4 and 24 hours later

### Method of measurement

Observation and examination

## 6

### Description

Pseudoaneurism

### Timepoint

Immediately after the homeostasis, 4 and 24 hours later

### Method of measurement

Observation and examination and sonography

## Intervention groups

### 1

#### Description

Patients in the intervention group admission is trained on how to take slow, deep breathing and 15 minutes before leaving again in terms of learning and doing clean properly controlled technique. To perform this procedure the patient is asked to breathe and exhale ratio 4: 6 do. The training face to face and to protect the tail of the expiration of counting used. Patients from 5 minutes before removing the sheet for 15 minutes , deep breathing and relaxation techniques to do. Patients will be asked to close your eyes while performing these techniques on how to do breathing and focus, as well as a hand on the abdomen and the other hand on their chest. Patients are taught to breathe through the nose and exhale through the mouth counts one to four, and act and do by counting from one to six . To ensure the patient will be asked to learn the technique for 1 minute in the presence of the researcher. All sheet for 5 minutes after starting slow, deep breathing and took out the tail end.

#### Category

Prevention

### 2

#### Description

In the control group, patients in the usual way and without the use of deep breathing and slow the sheet out.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Dr Shariati Hospital

#### Full name of responsible person

Zahra Yousefi

#### Street address

Jalale Ale Ahmad Highway

#### City

Tehrsn

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Zahra Yousefi

##### Street address

Arak University of Medical Sciences, Sardasht

##### City

Arak

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Arak University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

empty

#### Domestic or foreign origin

empty

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

empty

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr. Kobra Rahzani

##### Position

PhD in Nursing

##### Other areas of specialty/work

##### Street address

Shahid shiroodi Ave., Alamolhoda Ave.

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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master student of critical care nursing

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*