# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Jul 2026

## The effect of rhythmic breathing on pain intensity and anxiety in patients after coronary artery bypass graft surgery

## Protocol summary

**Study aim**
Determining the effect of rhythmic breathing on severity of pain and anxiety in patients after coronary artery bypass graft surgery

**Design**
This research is a clinical trial with a sample size of 102 people. The method of assigning the intervention to the subjects was randomized and random blocked blocks with block size 4 (using a random permutation table). The intervention used in this research According to a randomized list, a person outside the study who is not aware of research objectives and who is assigned a different code for sealed envelopes and assigned to any disease that is included in the study. In this way, the samples will be divided into two groups of intervention and control.

**Settings and conduct**
Icu section of Ahvaz Oil Hospital

**Participants/Inclusion and exclusion criteria**
Not being in a critical health condition Not having a history of taking sedative medicines and antidepressants The absence of known and diagnosed psychiatric illnesses by the physician Age of at least 30 and maximum 75 years

**Intervention groups**
The intervention group performs rhythmic respiration. The patient is asked to close his eyes, lie in the back position (soping), and count the numbers from 1 to 3 of the tail through the nose, then relieve the numbers from 1 to 3 breaths by counting them. Take 1 to 3 breaths through the mouth and focus only on entering and leaving the air during breathing. The control group will not receive any intervention.

**Main outcome variables**
Pain intensity؛ anxiety

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20181123041729N1**
Registration date: **2018-12-08, 1397/09/17**
Registration timing: **prospective**

Last update: **2018-12-08, 1397/09/17**
Update count: **0**

**Registration date**
2018-12-08, 1397/09/17

**Registrant information**

**Name**
Samereh Nasirnezhad

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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+98 61 3443 9964

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2018-12-11, 1397/09/20

**Expected recruitment end date**
2019-02-09, 1397/11/20

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The effect of rhythmic breathing on pain intensity and anxiety in patients after coronary artery bypass graft surgery

**Public title**
The effect of rhythmic breathing on pain intensity and anxiety in patients after coronary artery bypass graft surgery
**Purpose**
Supportive
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Patients undergoing coronary artery bypass graft surgery Age of at least 30 and maximum 75 years Not having a history of taking sedative medicines and antidepressants The absence of known and diagnosed psychiatric illnesses by the physician
**Exclusion criteria:**
having a history of taking sedative medicines and antidepressants The diagnosis of mental illness is documented
**Age**
From **30 years** old to **75 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **102**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
The method of assigning intervention to individuals was randomized and random blocked blocks with block size 4 (using the table for random permutations). The randomization list is provided by a statistic specialist. Blocking is usually used to create a balance in the number of specimens assigned to each of the studied groups. In this trial, there were two groups of 4 blocks consisting of 2 participants in the intervention group and 2 participants in the control group. The intervention used in this study according to a randomized list is provided by a person outside the study who is not aware of the research objectives and will be assigned a different code to the closed envelopes and will be allocated to any disease that is included in the study. In this way, a number of envelopes with an aluminum sleeve (for the lack of clarity of the contents of the envelopes) are prepared and each random sequence created on the card is recorded and the cards are inserted into the envelopes respectively. In order to maintain a random sequence, the numbering of envelopes on the outer surface is done in the same order. Finally, the door of the envelopes is pasted and placed in the box, respectively. At the time of the registration of the participants, one of the envelopes of the letter was opened in accordance with the order of the entry of the eligible participants, and the group allocated to it Participant will be revealed.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

### 1

**Registry name**
**Secondary trial Id**
**Registration date**
empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Ahvaz University of Medical Sciences
**Street address**
City university, Assistant Professor of Research and Technology Development, Ahvaz, Ground floor
**City**
Ahvaz
**Province**
Khouzestan
**Postal code**
6135715794
**Approval date**
2018-11-03, 1397/08/12
**Ethics committee reference number**
IR.AJUMS.REC.1397.570

## Health conditions studied

### 1

**Description of health condition studied**
Coronary artery Bypass Graft Patients
**ICD-10 code**
I25.1
**ICD-10 code description**
Atherosclerotic heart disease of native coronary artery

## Primary outcomes

### 1

**Description**
Pain intensity
**Timepoint**
On the first day of operation (after extubation and alertness of the patient) and on the second and third days of operation, every time before and after the intervention
**Method of measurement**
Visual Analogue Scale

**2**

**Description**
Anxiety
**Timepoint**
Speilberger Anxiety scale
**Method of measurement**
The second day of surgery before and after the intervention

## Secondary outcomes

**1**

**Description**
The amount of analgesic use
**Timepoint**
On the first, second and third days of action
**Method of measurement**
Through the checklist

## Intervention groups

**1**

**Description**
Intervention group: In the ICU section, the patient is asked to measure rhythmic pain on the first day of operation (after extubation and alertness of the patient) and on the second and third days of the operation, which will allow rhythmic breathing for 20 minutes every 5 minutes once and every time It takes one minute to complete the training three times a day. Every day before and after the intervention, the pain assessment questionnaire will be completed by the researcher and interview method. To measure the amount of anxiety, the second day of the operation requires patients to take the intervention three times a day according to the procedure described above. Before and after the intervention, the Spielberger anxiety inventory will be completed by the researcher.
**Category**
Treatment - Other

**2**

**Description**
Control group: No intervention will be performed. During the first, second and third day, the intensity of pain will be measured and the second day of anxiety will be measured.
**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Heart Surgery ward and ICU Heart of Ahvaz Oil Hospital
**Full name of responsible person**
Samereh Nasirnezhad
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Dr Mohammad Badvi
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University of Medical Sciences, Assistant Professor of Research and Technology, Jundishapur University of Medical Sciences and Health Services, Ahvaz, Ground floor
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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**
Ahvaz 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**
Ahvaz University of Medical Sciences

**Full name of responsible person**
Samereh Nasirnezhad

**Position**
Nursing Graduate Student

**Latest degree**
Bachelor

**Other areas of specialty/work**
Nursery

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## Person responsible for updating data

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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**
No - There is not a plan to make this available

**Statistical Analysis Plan**
No - There is not 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**
No - There is not a plan to make this available

**Data Dictionary**
Not applicable