

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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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Email address

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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

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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 Nasirnejad

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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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Other areas of specialty/work

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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