Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of controlled breathing on anxiety and fear in patients undergoing coronary angiography

Protocol summary

Study aim

The effect of controlled breathing on the anxiety and fear of patients candidate for coronary angiography admitted to Shahid Sadoughi Hospital, Yazd, in 1396

Design

This is a clinical trial study. The research community are all patients admitted to Shahid Sadoughi Hospital in Yazd for angiography. Among the research community, 80 patients select and divide randomly into two groups (case and control group).

Settings and conduct

In this study, a two-part questionnaire is used, the first part consists of demographic variables including age, sex, level of education and marital status. The second part relates to Spilberger's Situational Anxiety Questionnaire.

Participants/Inclusion and exclusion criteria

Inclusion criteria: -Informed consent - Age over 18 years - Ability to read and write in Persian language - GCS: 15 Exclusion criteria: - Having angiography history - Use of invasive methods, such as echocardiography from the esophagus before angiography - having heart valve disease, acute myocardial infarction and acute coronary syndrome - Neuropathy and Delirium - The presence of psychiatric disorders, the continued use of muscle relaxant, hypnotic, psychoactive and anxiolytic drugs in the last 6 months, according to the patient. - Drug addiction

Intervention groups

Control group: This group undergo Angiography without any training in controlled breathing. Intervention group: In this group, controlled breathing is trained and this breathing perform by the patients for 10 minutes before and also throughout the Angiography.

Main outcome variables

Anxiety; Fear

General information

Reason for update

Dear Editor In Chief The start date of my sampling was 05/01/2017 and the end date of my sampling was 01/09/2017. Unfortunately, due to repeated corrections, the final date of registration in the system was 11/07/1397. And now, unfortunately, I have trouble publishing the article. And the only problem mentioned is the registration date and I can not print anywhere. Please pay the necessary attention Thank you regards

Acronym

IRCT registration information

IRCT registration number: **IRCT20170701034825N2**
Registration date: **2019-01-27, 1397/11/07**
Registration timing: **prospective**

Last update: **2021-03-21, 1400/01/01**
Update count: **1**

Registration date

2019-01-27, 1397/11/07

Registrant information

Name
elham akhoondzadeh
Name of organization / entity
Shahid Sadoughi University of Medical Sciences Yazd
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Shahid Sadoughi University Of Medical Sciences Yazd

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date
2019-06-22, 1398/04/01
Actual recruitment start date
2019-02-20, 1397/12/01
Actual recruitment end date
2019-06-22, 1398/04/01
Trial completion date
2019-07-21, 1398/04/30

Scientific title
The effect of controlled breathing on anxiety and fear in patients undergoing coronary angiography

Public title
effect of controlled breathing on anxiety and fear in coronary angiography
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Informed consent Age over 18 years Candidate for angiography Ability to read and write in Persian GCS: 15
Exclusion criteria:
Having angiography history- Use of invasive methods, such as echocardiography from the esophagus before angiography having heart valve disease, acute myocardial infarction and acute coronary syndrome Neuropathy and Delirium The presence of psychiatric disorders the continued use of muscle relaxant, hypnotic, psychoactive and anxiolytic drugs in the last 6 months, according to the patient Drug addiction
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
After random sampling using table of random numbers among all eligible patients admitted to Shahid Sadoughi hospital in Yazd for angiography, research objectives are explained telephone and it is mentioned that they may be in the intervention or control group. then patients are divided randomly into two intervention and control groups (each of the groups 40 patients)
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
Shahid Sadoughi University of Medical Sciences Yazd
Street address
Bahonar square
City
Yazd
Province
Yazd
Postal code
8915887857
Approval date
2017-08-19, 1396/05/28
Ethics committee reference number
IR.SSU.REC.1396.72

Health conditions studied

1

Description of health condition studied
Angina pectoris
ICD-10 code
I20
ICD-10 code description
Angina pectoris

Primary outcomes

1

Description
anxiety
Timepoint
Immediately before intervention and immediately after intervention (both cases before performing angiography)
Method of measurement
Spielberger positional anxiety questionnaire

2

Description
fear
Timepoint
Immediately before intervention, five minutes after angiography and one day after angiography
Method of measurement
Using the VAS benchmark

Secondary outcomes

1

Description

Heart rate

Timepoint

Immediately before intervention, five minutes after angiography

Method of measurement

Physical exam

Intervention groups

1

Description

After a controlled breathing training, the participants in the intervention group are requested to use twenty minutes controlled breathing prior to angiography for ten minutes, as well as throughout the course of angiography. So they must inhale in 2 seconds, counting 1001, 1002 and exhale in 3 seconds, counting 1001, 1002, 1003 in their mind.

Category

Prevention

2

Description

Control group: There is no intervention in the control group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Sadoughi Hospital Yazd

Full name of responsible person

Elham Akhondzadeh

Street address

Shahid Sadoughi Hospital, Ebne sina Evenue, Shahid Ghandi BLVD, Yazd, Iran

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e.akhondzadeh@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Research deputy

Street address

Bahonar Square, Central office of Shahid Sadoughi University of Medical Sciences, Yazd

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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

Vice chancellor for research of Yazd Shahid Sadoughi 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

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Elham Akhoondzadeh

Position

Master degree nursing specialist student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person
Mostafa Javadi

Position
Ph.d. in nursing

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for updating data

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Position
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Latest degree
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Nursery

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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
There is no more information.

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
Yes - There is a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
A portion of the data including main and secondary outcomes will be shared.

When the data will become available and for how long
The relevant data will be available one year after the publication of the results.

To whom data/document is available
Data will be available to all groups that have the scientific capabilities of the data.

Under which criteria data/document could be used
If a person wants to have a similar study, he needs to have the data in this study. If a person intends to use the data from this study as an applied therapeutic topic.

From where data/document is obtainable
Ekham Akhondzadeh tel: 00989137790427 E mail: e.akhondzadeh@ssu.ac.ir

What processes are involved for a request to access data/document
Documentation will be provided to the applicant immediately after the submit application and the phone call or e-mail.

Comments