

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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)

Phone

+98 35 3525 0539

Email address

e.akhondzadeh@ssu.ac.ir

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

AgeFrom **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
City
Yazd
Province
Yazd
Postal code
8916978477
Phone
+98 35 3724 0171
Email
info@ssu.ac.ir
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 Akhondzadeh
Position
Master degree nursing specialist student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
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Unit 521, Shahid Ahmadi Roshan apartment, Safaie, Yazd
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Fax
Email
e.akhondzadeh@ssu.ac.ir
Web page address

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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College of Nursing Midwifery, Yazd Shahid sadoughi
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Web page address

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

Person responsible for updating data

Contact

Name of organization / entity

Yazd Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Elham Akhoondzadeh

Position

M.A Student of intensive care Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Boo Ali line, Timsar Fallahi street, Yazd, Iran

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