

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

The impact of Benson relaxation on the anxiety of patients experiencing coronary angiography

Protocol summary

Summary

Objectives:The purpose of this study will be determined the impact of Benson Relaxation on the anxiety level of patients experiencing coronary angiography. **Design:**This research will be a randomized clinical trial . **Setting and conduct:**This study will be performed on a group of 73 patients hospitalized in Mazandaran Heart Center for coronary angiography in 2014. who will be randomly selected. They will be divided in two subject (34) and control (33) groups. **Demographic data sheets,** Spielberger state-trait anxiety inventory and recording sheet of homodynamic variables will be distributed among the two groups before and after Benson Relaxation. **Inclusion criteria:** age of 30-90 years; undergoing coronary angiography for the first time; only undergoing coronary angiography; patients with full consciousness and not in critical conditions and having the ability to speak and hear **Exclusion criteria:** lack of patient consent to continue participation in the study;having received a sedative within the past 8 hours; history of treatment with procedures similar to muscular relaxation and suffering from muscle paralysis. **Intervention:**In relaxation group,One hour before angiography and immediately before the intervention, anxiety levels and vital signs will be recorded.This technique will be done, then anxiety levels and vital signs will be recorded after 30 minutes at the end of relaxation . The participants will be received routine care,. The control group will be received only routine care. Anxiety levels and vital signs will be measured 60 and 30 minutes prior to angiography. The main outcome measures will be anxiety.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110087067N2**

Registration date: **2015-12-30, 1394/10/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-30, 1394/10/09

Registrant information

Name

Homyra Tahmasebi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Islamic Azad University Sari Branch

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2014-12-21, 1393/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The impact of Benson relaxation on the anxiety of patients experiencing coronary angiography

Public title

The impact of Benson relaxation on the anxiety

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age of 30-90 years; undergoing coronary angiography for the first time; only undergoing coronary angiography; patients with full consciousness and not in critical conditions and having the ability to speak and hear
Exclusion criteria: lack of patient consent to continue participation in the study; having received a sedative within the past 8 hours; history of treatment with procedures similar to muscular relaxation and suffering from muscle paralysis.

Age

From **30 years** old to **90 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **73**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

How randomization was sealed envelope

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University Sari
Branch

Street address

7th km of sea Road(Farah Abad)

City

Sari

Postal code

Approval date

2014-08-13, 1393/05/22

Ethics committee reference number

1393-6

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F40.2

ICD-10 code description

Specific (isolated) phobias

Primary outcomes

1

Description

Anxiety

Timepoint

one hour and 30 minutes before the angiography

Method of measurement

Spielberger standard questionnaire

Secondary outcomes

1

Description

Blood pressure

Timepoint

Hour and 30 minutes before the angiography

Method of measurement

Sphygmomanometer

2

Description

Pulse

Timepoint

Hour and 30 minutes before the angiography

Method of measurement

Physical examination

3

Description

Respiratory

Timepoint

Hour and 30 minutes before the angiography

Method of measurement

Physical examination

Intervention groups

1

Description

Intervention group: In subject group (relaxation group), the audio file for relaxation exercises will be provided to the patients and the exercises will be performed by the patients simultaneously in the presence of the researcher on the day before angiography. One hour before angiography anxiety levels and vital signs will be recorded immediately before the intervention. They will be received routine care, providing a calm and quiet

environment and minimizing the environmental provocations, the patients will be listened to the audio file for relaxation techniques through headphones. In this technique, patients calmly lie on the bed with closed eyes and start to say the relaxing words (Like God; love; etc.) and mean while, deeply inhale through the nose and deeply exhale through the mouth and repeat the desired word in their mind and simultaneously relax their muscles from the fingertips upward until complete relaxation of all the muscles of the body. This condition will be maintained for 20 minutes and this technique was done before the angiography and then anxiety levels and vital signs will be recorded after 30 minutes at the end of relaxation.

Category

Prevention

2

Description

Control group: no intervention was done and only received routine care. Anxiety levels and vital signs were measured one hour and 30 minutes before the angiography. There was no intervention and placebo in this group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Mazandaran Heart Center

Full name of responsible person

Dr.Vahid Mokhberi

Street address

Army Blvd , Square Municipality

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mohamad Farsi

Street address

7th km of sea Road(Farah Abad)

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sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Homyra Tahmasebi

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0098

Fax**Email****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