

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of aromatherapy on anxiety of candidates for coronary angiography in Shahid Mohammadi Bandar Abbas Hospital in 2018

Protocol summary

Study aim

Determine the effect of aromatherapy on the anxiety of candidates for coronary angiography

Design

Double-blind clinical trial - A total of 80 patients - two intervention and control groups

Settings and conduct

This study is a double blind clinical trial (patients, carers, and analyst) that will be performed on patients undergoing coronary artery angiography which will be hospitalized in the post cath. of Shahid Mohammadi Hospital in Bandar Abbas. Units are randomly divided into two groups intervention and control. The control group will inhale the pads stained with 0.2 ml of the placebo and the intervention group of the mint essence impregnated pads as much as they will attach to the front of the sybase for 20 minutes. The level of anxiety and vital signs of the patient will be recorded before and after the intervention. A demographic questionnaire, a Spielberger standard questionnaire, and a vital signs registration form will be used to collect information.

Participants/Inclusion and exclusion criteria

Entry requirements: For the first time, only undergo angiography. Not heart valve disease, full alert, lack of vision and hearing And olfactory, liver, kidney, respiratory, allergy and psychologic disease , no addiction, age range of 18-60 years, no use of sedative drugs 4 hours before intervention. Conditions of exclusion: Not participating in the study, changes in vital signs and cardiac dysrhythmia .Not having the criteria for entering the study.

Intervention groups

The control group in room 1; having a non-absorbent eye pad and 0.2 ml normal saline attached to the chest is studied for 20 minutes; the same procedure will go on for intervention group in room 2, actually peppermint oil of Barij essence company will be used instead at 0.2 ml for eye pads.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

رایحه درمانی

IRCT registration information

IRCT registration number: **IRCT20190225042844N1**

Registration date: **2019-03-09, 1397/12/18**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-09, 1397/12/18**

Update count: **0**

Registration date

2019-03-09, 1397/12/18

Registrant information

Name

Roghaye Koohestani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3366 7904

Email address

roghayekoohestani2028@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-01, 1397/12/10

Expected recruitment end date

2019-04-30, 1398/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy on anxiety of candidates for coronary angiography in Shahid Mohammadi Bandar Abbas Hospital in 2018

Public title

The study effect of aromatherapy on anxiety

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

For the first time undergo coronary artery angiography. Only undergo coronary artery angiography. Before undergoing angiography, they are not subjected to other invasive methods such as echocardiography Not having heart valve disease. All units have full vigilance and are not in severe conditions. There is no visual and hearing loss and no smell. Not having respiratory and allergic problems. Not having drug additction. There is no liver and kidney problems. The age range is between 18 - 60 years old. Do not take sedative medicines 4 hours before the intervention. Not having a history of mental illness.

Exclusion criteria:

Unwilling to participate in the study. Allergic to peppermint oil With the risk of dysrhythmia.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The units are divided randomly into two intervention and control groups using the random allocation software. In this table, numbers from 1 to 80 are classified where each number belongs to a group (intervention or control) that is randomly assigned to that group. The first case will be assigned to one number and its associated group, and the rest of the samples will be included in the study accordingly.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients and carers do not know which patient will fall into any of the groups (aromatherapy or controls). Because the data is encoded, the data analyzer is also blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Bandar Abbas University of Medical Sciences

Street address

Research and Technology Dept., Shahid Mohammadi Hospital, Shahid Chamran Blvd.

City

Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Approval date

2019-02-25, 1397/12/06

Ethics committee reference number

IR.HUMS.REC.1397.300

Health conditions studied**1****Description of health condition studied**

Anxiety in patients undergoing angiography

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes**1****Description**

Anxiety

Timepoint

An hour before angiography and after intervention

Method of measurement

Spielberger questionnaire

Secondary outcomes**1****Description**

Systolic Blood Pressure

Timepoint

An hour before angiography and after intervention

Method of measurement

Dial Sphygmomanometer

2

Description

Dyastolic Blood Pressure

Timepoint

An hour before angiography and after intervention

Method of measurement

Dial Sphygmomanometer

3

Description

pulse

Timepoint

An hour before angiography and after intervention

Method of measurement

Chronometer

4

Description

Respiratory

Timepoint

An hour before angiography and after intervention

Method of measurement

Chronometer-Inspection the movements of the chest

Intervention groups

1

Description

Intervention group: An hour prior to angiography, the patient's vital signs will be monitored and the demographic and Spielberger questionnaires will be completed, then the pads stained with 0.2 ml of peppermint essential oil will be attached to the front of the chest at the concentration of 100% of the baricha essence of Kashan. It will be inhaled for 20 minutes. Then, the vital signs are checked and the Spielberger question will be completed.

Category

Treatment - Drugs

2

Description

Control group: An hour prior to angiography, the patient's vital signs will be monitored and the demographic and Spielberger questionnaires will be completed, then pads stained with 0.2 ml of normal saline will be attached to the front of the chest and will be inhaled for 20 minutes. The Spielberger control and question will be completed.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Roghaye Koohestani

Street address

Shahid Mohammadi Hospital, Shahid Chamran Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Timur Aga Molaei

Street address

Research and Technology Dept., Shahid Mohammadi Hospital, Islamic Republic of Iran Blvd.

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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

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Roghaye Koohestani

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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School of Nursing and Midwifery, Southern Resalat Ave.

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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Person responsible for updating data**Contact****Name of organization / entity**

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available