

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of orange blossom aroma therapy on physiological parameters and anxiety in patients with coronary artery diseased admitted for angiography In2017

Protocol summary

Summary

Diagnostic coronary angiography, is an invasive cardiovascular diagnosis of coronary artery disease. The aim of this study was to determine the effect of sour orange aromatherapy on physiological indexes and stress in Cardiac patients admitted to coronary angiography. Inclusion criteria: patient willingness to participate in the study; Smell test positive, patients who are undergoing coronary angiography for the first time; patients who are not taken nitrate and housing from 6 hours ago, do not have allergies and determine which factors like hospitalization and treatment for mental health problems. Exclusion criteria: history of drug addiction; the disorders of smell and patients who underwent an emergency are angiogenesis. This study would be a randomized clinical trial of the two groups in 2017, Research community will be patients Hospitalized in cardiac angiography Heshmat Hospital in Rasht, with a sample size of 36 participants in each group. All three forms to collect demographic, physiological, standard anxiety questionnaire "Speal Berger" will be used. First, using a standard anxiety questionnaire " Speal burger", patients is known with high levels of anxiety (over 43), then Will be in the group with aromatherapy or without it by simple random sampling. To compare the two groups, including the pre-test, analysis of variance will be used and to examine the relationship between qualitative variables, Chi-square test will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017051133808N1**

Registration date: **2017-06-14, 1396/03/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-14, 1396/03/24

Registrant information

Name

Parand Pourghane

Name of organization / entity

Guilan university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Guilan university Of Medical Sciences, Rasht, Iran

Expected recruitment start date

2017-06-01, 1396/03/11

Expected recruitment end date

2018-06-01, 1397/03/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of orange blossom aroma therapy on physiological parameters and anxiety in patients with coronary artery diseased admitted for angiography In2017

Public title

The effect of aroma therapy on physiological parameters and anxiety in patients with coronary artery diseased

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: The willingness of the patient to participate in the study; patients first underwent coronary angiography placed before angiography; under other methods of invasive Transesophageal echocardiography; not be 6 hours ago nitrate and housing consumption; are not allergies; rhinitis allergic; eczema and respiratory problems have not; before the intervention, no history of headache; perfume or cologne before or during treatment; not experience stress event acute over the past 6 months; and no history of hospitalization and treatment; not because of psychological problems. Also, testing positive smell (the ability to detect the smell of aromatherapy desired solution and Pleasure it is the other inclusion criteria. Exclusion criteria: having a history of drug addiction According expressed by the patient; as well as having disorders; colds and nasal congestion that affect the sense of smell; the study exclusion criteria will be considered. Also, patients who underwent an emergency angiography are enrolled STEMI patients do not like.

Age

From **19 years** old to **59 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan university Of Medical Sciences

Street address

Gas field, martyr Beheshti Blvd, in front of the West Bank Sepah , on behalf of Radiator Vice Chancellor for Research and Technology, Guilan, Rasht, Iran

City

Rasht

Postal code

Approval date

2017-04-22, 1396/02/02

Ethics committee reference number

IR.GUMS.REC.1395/348

Health conditions studied

1

Description of health condition studied

Patients with Coronary Artery Disease

ICD-10 code

I24.0

ICD-10 code description

Coronary thrombosis not resulting in myocardial infarction

Primary outcomes

1

Description

Anxiety

Timepoint

Half an hour before - Half an hour later

Method of measurement

The State-Trait Anxiety Inventory

2

Description

Physiological parameters

Timepoint

Half an hour before and half an hour later

Method of measurement

blood pressure with Sphygmomanometer, Pulse counting with touch of the radial artery, , respiration rate based looking at the numbers going up and down the chest, temperature control based with thermometer

Secondary outcomes

empty

Intervention groups

1

Description

For the control group, does not the intervention

Category

N/A

2

Description

For the control group, does not the intervention

Category

N/A

3

Description

First, using a standard anxiety questionnaire "Steel standard questionnaire Burger", patients with high levels of anxiety (over 43) will be recognized. Then, these people will be with simple random sampling in the group will be aromatherapy or without it. During aromatherapy for patients, Researchers will try to accuracy in conducting research on aromatherapy aimed lack of awareness of other patients in the group Without aromatherapy. Essential oil used licensed by Ministry of Health with code: 16210/34 Series also includes the construction of 5027 and its compounds: linalool, linalyl acetate, propylene glycol, Jranlyvl, oil and phenyl ethyl alcohol Petit Green. Before leaving for angiography, completed demographic questionnaires and measured their anxiety. That 3 drops of essential oil of Citrus aurantium using the dropper on the balls of cotton in a container volume of 10 mL spinner and recommended distance of 5 cm nose, hold for 3 minutes and sniffed the half hours after vital signs monitor and recorded by a nurse and then will be transferred to the angiography room.

Category

Prevention

4

Description

First, using a standard anxiety questionnaire "made burger", patients with high levels of anxiety (over 43) will be recognized. Then, these people, simple random sampling in the group will be aromatherapy or without it. Essential oil used licensed by Ministry of Health with code: 16210/34 Series also includes the construction of 5027 and its compounds: linalool, linalyl acetate, propylene glycol, Jranlyvl, oil and phenyl ethyl alcohol Petit Green. Before leaving for angiography, completed demographic questionnaires and measured their anxiety. That 3 drops of essential oil of Citrus aurantium using the dropper on the balls of cotton in a container volume of 10 mL spinner and recommended distance of 5 cm nose, hold for 3 minutes and sniffed the half hours after vital signs monitor and recorded by a nurse and then will be transferred to the angiography room.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Angiography Heart Hospital glory, Guilan, Rasht

Full name of responsible person

Parand Pourghane

Street address

Gas field in front of Radiator Vice, Chancellor for Research and Technology, Guilan, Rasht

City

rasht

2

Recruitment center

Name of recruitment center

Heart Hospital glory, Guilan, Rasht

Full name of responsible person

Street address

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Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan university Of Medical Sciences

Full name of responsible person

Fatemeh Zaer Sabet

Street address

Street Namgoo, University of Education Of Medical Sciences, , Guilan, Rasht

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Guilan university Of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Guilan university of Medical Sciences

Full name of responsible person

Fatemeh Zaer Sabet

Street address

University of Education of Medical Sciences, Street Namgoo, Guilan, Rasht

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Guilan university of Medical Sciences

Proportion provided by this source

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
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Person responsible for general inquiries

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Person responsible for updating data

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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