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 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

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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 disease

**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 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**
- Single blinded

**Blinding (investigator's opinion)**
- Not used

**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**
- 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
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, Jranyvl, 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.

### 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**: empty
   - **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
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   - **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
Person responsible for general inquiries

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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