Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effect of Aroma inhalation Melissa officinalis on Anxiety level and Physiological Parameters of patients Undergoing Coronary Angiography - Kordkoy Heart Hospital –Winter 2020

Protocol summary

Study aim
Determining the effect of Aroma inhalation Melissa officinalis on anxiety level and physiological parameters of patients undergoing coronary angiography

Design
A clinical trial with the control group, randomized, phase 3 on 72 patients. A four-block random assignment will be used to assign samples to groups.

Settings and conduct
After that, people are divided into two groups of control and case of 36 people by simple randomization method. Intervention in the intervention group will be aromatherapy with Melissa officinalis essential oil (essential oil that will be prepared by the plant company of essential oil will be used). Three drops of essential oil are placed on 2. 2 pieces of gas and attached to the patient's collar for 20 minutes. In the control group, distilled water will be used instead of lemon balm essential oil.

Participants/Inclusion and exclusion criteria
Inclusion criteria will be: age over 35 years; Candidate angiography patients; Having informed consent and completing a written consent; Having a healthy sense of smell Inclusion criteria: previous angiography history; previous diagnosis of valvular heart disease; mental health problems; history of plant allergies

Intervention groups
After that, people are divided into two groups of control and case of 36 people by simple randomization method. Intervention in the intervention group will be aromatherapy with Melissa officinalis essential oil (essential oil that will be prepared by the plant company of essential oil will be used). Three drops of essential oil are placed on 2. 2 pieces of gas and attached to the patient's collar for 20 minutes. In the control group, distilled water will be used instead of lemon balm essential oil.

Main outcome variables
Respiratory rate; Systolic blood pressure; Diastolic blood pressure; Anxiety

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20161031030616N3**
Registration date: **2022-10-12, 1401/07/20**
Registration timing: **retrospective**

Last update: **2022-10-12, 1401/07/20**
Update count: **0**

Registration date
2022-10-12, 1401/07/20

Registrant information
Name
Fatemeh Kolangi
Name of organization / entity
Babol University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-04-04, 1400/01/15
Expected recruitment end date
2021-06-05, 1400/03/15
Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Aroma inhalation Melissa officinalis on Anxiety level and Physiological Parameters of patients Undergoing Coronary Angiography - Kordkoy Heart Hospital –Winter 2020

Public title

The Effect of Aroma inhalation Melissa officinalis on anxiety before cardiac angiography

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 35 years Patients undergoing angiography Having a healthy sense of smell Having informed consent and completing a written consent

Exclusion criteria:

History of previous coronary angiography Previous diagnosis of heart valve disease Having mental health problems History of allergy to plants

Age

From **35 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals are divided into control and case groups by simple randomization method. Samples will be selected as available. A four-block random assignment will be used to assign samples to groups. Therefore, we will have 6 blocks that the order of allocating samples in groups is (AABB-ABAB-ABBA-BAAB-BABA-BBAA). Each of the blocks is assigned numbers from one to six. Randomly selected from 1 to 6 digits. Select the block corresponding to the desired number and assign the patients to the two groups according to the block. Write numbers 1 to 6 on a piece of paper and put them in the glass. Randomly, one of the papers will be selected from the glass. Corresponding to the number on the sheet, the desired block of text is taken out and according to the permutations of the block, samples are assigned to two groups(In the intervention group, and in the control group).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

NO

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

Street address

Phalsaphy complex, Shast kola Road

City

Gorgan

Province

Golestan

Postal code

4918936316

Approval date

2021-02-01, 1399/11/13

Ethics committee reference number

IR.GOUMS.REC.1399.340

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

Anxiety

Timepoint

Once before exposure and the second time for the third minute of aromatherapy

Method of measurement

Stilberger Questionnaire

Secondary outcomes

1

Description

Hemodynamic changes

Timepoint

Once before exposure and the second time for the third minute of aromatherapy

Method of measurement
Monitoring device

2

Description
Respiratory rate
Timepoint
Once before exposure and the second time for the third minute of aromatherapy
Method of measurement
Monitoring device

Intervention groups

1

Description
Intervention group: Three drops of lemon balm essential oil are placed on a 2 × 2 piece of gas and will be attached to the patient's collar for 20 minutes.
Category
Treatment - Drugs

2

Description
Control group: Three drops of distilled water are placed on a 2 × 2 piece of gas and will be attached to the patient's collar for 20 minutes.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kordkoy Heart Hospital
Full name of responsible person
Mehdi Zahedi
Street address
Jangal Street, above Amir Al-Momenin Square
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Fax
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Vice-chancellor of Research and Technology of Gorgan University
Street address
Vice-chancellor of Research and Technology, Gorgan University of Medical Sciences, 5 Km Gorgan, Sari Road
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Phone
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Email
Info@goums.ac.ir
Web page address
http://goums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Fatemeh Kolangi
Position
Specialist faculty member
Latest degree
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Person responsible for updating data

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