

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 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)

Phone

+98 11 3219 4730

Email address

f.kolangi@mubabol.ac.ir

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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48818 99441

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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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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

Ph.D.

Other areas of specialty/work

Traditional Medicine

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

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Full name of responsible person

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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