

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Impact of inhalation aromatherapy with damask rose on stress, anxiety and hemodynamic parameters of patients undergoing coronary angiography One-blind randomized clinical trial in two groups (intervention and placebo)

Protocol summary

Summary

Purpose: To determine the effect of inhaled aromatherapy on stress, anxiety and hemodynamic parameters of patients undergoing coronary artery angiography. Design: A single-blind randomized clinical trial. How to do Candidate patients for coronary angiography in the angiographic section will be included in the following criteria: (a) first time angiography; (b) lack of critical clinical conditions; (c) non-compliance with angioplasty; (d) lack of alcohol and narcotic addiction; (E) Full person alertness and ability to answer the questioner's questions; (i) Absence of diagnosed anxiety disorder based on the physician's opinion. Patients with the following criteria will be excluded from the study: (a) aromatherapy intolerance for any cause; (b) any disorder or instability in the state of consciousness or hemodynamic Leads to the impossibility of continuing the study; (c) the reluctance to continue to participate in Study. Interventions: In the intervention group, an aroma of five drops of 40% Rose Essence is made by attaching absorbent Cloth to the patient's collar for 20 minutes. In the placebo group, five drops of water are placed on the absorbent Cloth attached to the patient's collar for 20 minutes. Main outcome measurement: Stress, anxiety and hemodynamic variables with the following questionnaires will be considered. (A) Stress is measured by the stress section of the dass21 questionnaire; (b) Anxiety is measured by the anxiety section of the dass21 questionnaire; (c) After measuring the hemodynamic variables (systolic blood pressure, diastolic blood pressure, mean arterial blood pressure, heart rate and respiration) with a monitoring device and a clock, it is recorded on the check list.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201702019759N8**

Registration date: **2017-07-31, 1396/05/09**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-31, 1396/05/09

Registrant information

Name

Ali Bikmoradi

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0439

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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor of Research and Technology, Hamadan University of Medical Sciences

Expected recruitment start date

2017-08-22, 1396/05/31

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Impact of inhalation aromatherapy with damask rose on stress, anxiety and hemodynamic parameters of patients undergoing coronary angiography One-blind randomized clinical trial in two groups (intervention and placebo)

Public title
The impact of the aromatherapy with damask rose on stress, anxiety and hemodynamic parameters of patients undergoing angiography

Purpose
Supportive

Inclusion/Exclusion criteria
Candidate patients for coronary angiography in the angiographic section will be included in the following criteria: (a) first time angiography; (b) lack of critical clinical conditions; (c) non-compliance with angioplasty; (d) lack of alcohol and narcotic addiction; (E) Full person alertness and ability to answer the questioner's questions; (i) Absence of diagnosed anxiety disorder based on the physician's opinion. Patients with the following criteria will be excluded from the study: (a) aromatherapy intolerance for any cause; (b) any disorder or instability in the state of consciousness or hemodynamic Leads to the impossibility of continuing the study; (c) the reluctance to continue to participate in Study

Age
From **18 years** old to **64 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Single

Other design features
In this study, we will use balanced block randomization and patients will be allocated in intervention group (aromatherapy) and control (inhalation of distilled water). Blinding will done for research analysing committee.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Fahmideh St., Hamadan University of Medical Sciences

City

Hamadan

Postal code

6517838698

Approval date

2017-06-17, 1396/03/27

Ethics committee reference number

IR.UMSHA.REC.1396.249

Health conditions studied

1

Description of health condition studied

Stress

ICD-10 code

F43.0

ICD-10 code description

Acute stress reaction

2

Description of health condition studied

Atherosclerotic heart disease

ICD-10 code

I25.1

ICD-10 code description

I25.1

3

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

4

Description of health condition studied

Coronary angiography

ICD-10 code

(Y70-Y82)

ICD-10 code description

Medical devices associated with adverse incidents in diagnostic and therapeutic use

Primary outcomes

1

Description

Hemodynamic parameter

Timepoint

Before and after the intervention

Method of measurement

Using a heart monitor and a clock

2

Description

Stress

Timepoint

Before and after the intervention

Method of measurement

Using the stress section of the dass questionnaire 21

3

Description

Anxiety

Timepoint

Before and after the intervention

Method of measurement

Using the anxiety section of DASS 21 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group, patients inhale five drops of 40% Rosa Damascus Essence on absorbent Cloth attached to their collar for 20 minutes.

Category

Treatment - Drugs

2

Description

In the placebo group, patients inhale five drops of distilled water are placed on an absorbent cloth attached to their collar for 20 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Beasat Therapeutic and Educational Center of Hamadan

Full name of responsible person

Azad Fatahi

Street address

Nursing and Midwifery School, Hamadan University of

Medical Sciences, Shaheed Fahmideh Ave

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor of research and technology

Full name of responsible person

Dr. Saeed Bashirian

Street address

Fahmideh ave., Deputy of research and technology, Hamadan University of Medical |Sciences

City

Hamadan

Grant name

از محل یک درصد بودجه طرح های تحقیقاتی دانشگاه

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor of research and technology

Proportion provided by this source

100

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

Person responsible for general inquiries

Contact

Name of organization / entity

School of public health, Hamadan University of Medical Sciences

Full name of responsible person

Dr. Ali Bikmoradi

Position

Associate professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

PhD of Medical management/Associate professor

Other areas of specialty/work

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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