

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effects of Aromatherapy with *Melissa Officinalis L.* on Anxiety of Patients candidate for coronary angiography and their spouses

Protocol summary

Study aim

Determination of the effect of aromatherapy with *Melissa officinalis L.* on anxiety and Physiologic parameters of patients candidate for coronary angiography and their spouses at Koosar hospital of Semnan city.

Design

The second phase of the clinical trial with control groups and a parallel group design that will be conducted by age stratified (18-45 years and older than 45 years) randomized block design with a sample size of 72 couples.

Settings and conduct

This study will be done at men internal ward of Koosar hospital in Semnan city.

Participants/Inclusion and exclusion criteria

Inclusion criteria includes: age of 18 and above, Literacy at least end of elementary education, being married, No previous history of coronary angiography, healthy olfactory sense, No drug addiction, No history of asthma and allergies. Exclusion criteria includes: Use of sedatives and anxiolytic drugs, Use of any perfume or fragrance

Intervention groups

Intervention group 1: 36 male with eligible criteria. Intervention group 2: 36 wives of intervention group 1 participants. Control group 1: 36 male with eligible criteria. Control group 2: 36 wives of control group 1 participants. Intervention, involves inhaling a cotton ball impregnated with 3 drops of 1% essential oil of *Melissa Officinalis L.* (manufactured by Abatage Pharmaceutical Company) attach to the collar of the cloth for 20 minutes. The control groups will use a cotton ball impregnated with sterile water attach to the collar for 20 minutes.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140721018550N8**

Registration date: **2020-01-28, 1398/11/08**

Registration timing: **prospective**

Last update: **2020-01-28, 1398/11/08**

Update count: **0**

Registration date

2020-01-28, 1398/11/08

Registrant information

Name

Nayyereh Raiesdana

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 3867

Email address

nr_dana@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-04, 1398/11/15

Expected recruitment end date

2020-08-05, 1399/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Aromatherapy with Melissa Officinalis L. on Anxiety of Patients candidate for coronary angiography and their spouses

Public title

Effects of Aromatherapy with Melissa Officinalis L. on Anxiety

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 18 years Literacy at least end of elementary education Being married No previous history of coronary angiography No olfactory deficiency No previous history of asthma and allergies No addiction

Exclusion criteria:

Use of sedatives or anxiolytic drugs Use of any perfume and fragrance Severe changes in vital signs or medical condition

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **72**

More than 1 sample in each individual

Number of samples in each individual: **2**

36 eligible men and their spouses were included in the intervention groups and 36 eligible men and their spouses were placed in the control groups.

Randomization (investigator's opinion)

Randomized

Randomization description

To ensure matching between the two groups as well as to achieve a completely random and balanced assignment, we will use a randomized classification using Stratified permuted block randomization. Individuals are then divided into two stratum of age 18-45 years and over 45 years, and for each class a separate random assignment is continued until the sample size is reached. For random assignment in each class based on different sequences of two methods A (intervention) and B (control), 6 blocks are defined and numbered from left to right from 1 to 6. Then using 1 to 6 random blocks of blocks are randomly selected. (Numbers 0, 7, 8 and 9 are not decided). Thus, the assignment type is determined from left to right, respectively. Since we need 36 pairs in each group, we have to randomly select the block 9 times for that class).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Bolverd, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3513138111

Approval date

2019-10-22, 1398/07/30

Ethics committee reference number

IR.SEMUMS.REC.1398.157

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F09

ICD-10 code description

Mental disorders due to known physiological conditions

Primary outcomes

1

Description

Anxiety

Timepoint

Before and after intervention

Method of measurement

Spielberger state-trait anxiety inventory(STAI) Scale

Secondary outcomes

1

Description

Systolic and diastolic blood pressure

Timepoint

Before and after intervention

Method of measurement

Non-invasive blood pressure measurement with Monitoring SAADAT

2

Description

Pulse rate

Timepoint

Before and after intervention

Method of measurement

Monitoring SAADAT

3

Description

O2 Saturation

Timepoint

Before and after intervention

Method of measurement

Pulse Oximeter Monitoring SAADAT

4

Description

Body temperature

Timepoint

Before and after intervention

Method of measurement

Digital Tympanic Thermometer (Beurer Mark)

Intervention groups

1

Description

Intervention group 1: Participants will inhale 3 drops of 1% essence of lemon balm on a cotton ball attached to the collar for 20 minutes in sitting position. Then Immediately after this time, State anxiety and their physiological indices will be measured and recorded with same instruments.

Category

Prevention

2

Description

Intervention group 2: Participants will inhale 3 drops of 1% essence of lemon balm on a cotton ball attached to the collar for 20 minutes in sitting position. Then Immediately after this time, State anxiety and their physiological indices will be measured and recorded with same instruments.

Category

Prevention

3

Description

Control group1: Participants will inhale 3 drops of sterile water on a cotton ball attached to the collar for 20 minutes in sitting position. Then Immediately after this time, State anxiety and their physiological indices will be measured and recorded with same instruments.

Category

Placebo

4

Description

Control group 2: Participants will inhale 3 drops of sterile water on a cotton ball attached to the collar for 20 minutes in sitting position. Then Immediately after this time, State anxiety and their physiological indices will be measured and recorded with same instruments.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Semnan Kowsar hospital

Full name of responsible person

Dr.Mohammad Memarian

Street address

Amin Blvd.,Semnan

City

Semnan

Province

Semnan

Postal code

3519899951

Phone

+98 23 3104 3200

Email

draria2018@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Parviz kokhaei

Street address

Deputy of Research and Technology, Semnan University of Medical Sciences, Basij boulevard, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Email

kokhaei@semums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Nayyereh Raiesdana

Position

Assistant professor.Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Semnan University of Medical Sciences, 5th Kilometer of Damghan road, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3513138111

Phone

+98 23 3365 4190

Fax

+98 23 3365 4209

Email

nr_dana@semums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Nayyereh Raiesdana

Position

Faculty member(Assistant professor)

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Semnan University of Medical Sciences, 5th Kilometer of Damghan road,

Semnan, Iran
City
Semnan
Province
Semnan
Postal code
3513138111
Phone
+98 23 3365 4190
Email
nr_dana@semums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Nayyereh Raiesdana

Position

Assistant professor.Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Faculty of Nursing and Midwifery, Semnan University of Medical Sciences, 5th Kilometer of Damghan road, Semnan, Iran

City

Semnan

Province

Semnan

Postal code

3513138111

Phone

+98 23 3365 4190

Fax

+98 23 3365 4209

Email

nr_dana@semums.ac.ir

Web page address

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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

Not applicable

Data Dictionary

Not applicable