

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The effect of inhalation aromatherapy with rose essential oil on anxiety level in patient undergoing coronary surgery

Protocol summary

Summary

We will conduct a single-blind randomized controlled trial to investigate the effect of inhalation aromatherapy with rose essential oil on the level of anxiety in patients before coronary artery bypass graft surgery. 66 patients will participate in this study and will divide into control and test groups. The patients in the test group, will inhale three drops of 4% rose essential oil that produced by Barij Essen's Co. Iran (kashan) for 10 min night and morning before surgery and the patients in control group will be done routine cares. The level of anxiety will be evaluated by Spielberger's Anxiety questionnaire before and 30 minutes after intervention in the control and test groups. Main inclusion criteria are desiring to participate in the study, Insensitivity to essential oils and aromas, have age Equal or above 18 years old , be candidate for coronary bypass graft surgery. Main Exclusion criteria include showing allergy to rose essential inhalation during the study, Occurrence of respiratory problems during intervention, unwillingness to participate in or continue the study. In this study will investigated the effect of inhalation aromatherapy with rose essential oil on the level of anxiety in patients before coronary artery bypass graft surgery

General information

Acronym

:

IRCT registration information

IRCT registration number: **IRCT2017091919677N5**

Registration date: **2017-11-13, 1396/08/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-13, 1396/08/22

Registrant information

Name

Ravanbakhsh Esmaeili

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3336 7345

Email address

r.esmaeili@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Deputy of Research of Mazandaran University of Medical Sciences

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of inhalation aromatherapy with rose essential oil on anxiety level in patient undergoing coronary surgery

Public title

The effect of inhalation aromatherapy with rose essential oil on anxiety level in patient undergoing coronary surgery

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: The desire to participate in the study:

Insensitivity to essential oils and aromas: have age Equal or above 18 years old: be candidate for coronary artery bypass graft surgery. Inclusion criteria: showing allergy to rose essential inhalation during the study: Occurrence of respiratory problems during intervention: unwillingness to participate in or continue the study.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 66

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
The blocking method will be used for random allocation in groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran university of Medical sciences

Street address

Mazandaran university of medical science,vice chancellor for resea

City

SARI

Postal code

4764996893

Approval date

2017-09-13, 1396/06/22

Ethics committee reference number

IR Mazums. Rec.10234

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F50-F59

ICD-10 code description

Behavioural syndromes associated with physiological disturbances and physical

Primary outcomes

1

Description

Anxiety

Timepoint

Immediately before intervention,The night before the operation,one hour before operation

Method of measurement

spielberger Anxiety questionnaire

Secondary outcomes

1

Description

Respiratory sensation and shorthness of breath

Timepoint

The night before the operation,One hour before operation

Method of measurement

Self-report questionnaire on possible complications

Intervention groups

1

Description

intervention group: 3 drop of essential oils of 4% rose manufacturing of Pharmaceutical Company Barij essence with manufacturing number 714043, will be shed by the dropper on the non absorbent cotton and at a distance of 20 cm from the patients nose. This will be attached to the patients clothes.The patients will be reacquired to inhale the breath of the scent.

Category

Other

2

Description

Control group: The routine cares will be done in this patients.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mazandaran Heart Center Hospital

Full name of responsible person

Fatemeh Fazlollahpoor

Street address

Mazandaran Heart Center Hospital, Artesh Blvd, sari,
Mazandaran

City

Sari

Fax**Email**

f.fazlollahpoor@gmail.com

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for Research Mazandaran University
of Medical Sciences

Full name of responsible person

Majid Saeedi(vicor)

Street address

Vice Chancellor for Research Mazandaran University
of Medical Sciences, Moalem Street, Moalem Square,
Sari, Iran

City

Sari

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice Chancellor for Research Mazandaran University of
Medical Sciences

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**

Mazandaran University of Medical Sciences - Faculty
of Nursing and Midwifery Nasseibeh

Full name of responsible person

Fatemeh Fazlollahpoor

Position

Student of Master of Critical Care Nurses

Other areas of specialty/work**Street address**

Nasseibeh Nursing & Midwifery Faculty, vesal Street,
Amir Mazandarani Blvd, Sari, Mazandaran

City

Sari

Postal code

4764996893

Phone

+98 11 4220 1376

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

Mazandaran University of Medical Sciences

Full name of responsible person

Ravanbakhsh Esmaeili

Position

Assistant Professor

Other areas of specialty/work**Street address**

Nasseibeh Nursing & Midwifery Faculty, Vesal Street,
Amir Mazandarani Blvd, Sari, Mazandaran

City

Sari

Postal code

4816713445

Phone

+98 11 3325 7230

Fax**Email**

r.esmaeili@mazums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Fatemeh Fazlollahpoor

Position

Student of Master of Critical Care Nurses

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Nasseibeh Nursing & Midwifery Faculty, Vesal Street,
Amir Mazandarani Blvd, Sari, Mazandaran

City

Sari

Postal code

4764996893

Phone

+98 11 4220 1376

Fax**Email**

f.fazlollahpoor@gmail.com

Web page address**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