Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of inhalation of aroma blend containing Lavender, Roman chamomile and Neroli on anxiety and vital signs of Acute Coronary Syndrome patients

Protocol summary

Summary

Goal of study:The effect of combined inhaled combination of lavender, chamomile and Neroli on anxiety in patients with acute coronary syndrome. A one blinded randomized clinical trial with control group. Study population: All patients with acute coronary syndrome at their second day of hospitalization in coronary care unit of Sajjad Hospital (a general hospital affiliated to Iran University of Medical Sciences) The eligible patients will be randomly assigned to the aromatherapy, placebo and control groups using randomization . Allocation:25 patients in each group.Aromatherapy, placebo, control groups Both patients and interviewers were unaware of the treatment each patient had received.The medication will be given to the patients by researcher and the effect of treatments will be evaluated by another researcher independently. Intervention:In the aroma group, two drops of the blend of lavender, roman chamomile and Neroli oils at a ratio of 6:2:0/5 will be shed on pad eyes and the patients are asked from a distance of 5 cm inhale through 10 deep breaths at 7 pm and the aroma pad will be placed under the patients pillow until the following morning. In the placebo group, patients will be received two drops of distilled water as a placebo on pad eyes at the same time and method of the aroma group. The control group will be received conventional nursing care. The demographic data form and state and trait anxiety with Spielberger inventory and base vital signs data will be completed on the evening of intervention day. Anxiety level will be measured 30 minutes after intervention, at 7:30 pm and will be assessed at 7 am in the day following intervention. Vital signs(systolic and diastolic pressure, pulse and respiration) will be measured once 30 minutes after intervention and 3 times (each 4 hours) after the procedure, in each groups .

General information

Acronym

ACS:Acute Coronary Syndrom

IRCT registration information

IRCT registration number: **IRCT2015073023419N1**
Registration date: **2016-01-17, 1394/10/27**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-01-17, 1394/10/27

Registrant information

Name

Raheleh Rahmani

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of inhalation of aroma blend containing Lavender, Roman chamomile and Neroli on anxiety and vital signs of Acute Coronary Syndrome patients

Public title

The effect of Aromatherapy on anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 20-80 years; established diagnosis of Unstable Angina and Miocardial Infarction; not having cardiomyopathy; no indication of cardio pulmonary resuscitation; no history of smelling impairments, allergic, rhinitis, eczema, herbal or essence allergic, respiratory disease such as asthma, anxioligic or mental disorders; close relatives death in recent one month; obtaining a score of more than 20 in the Speilberger State Anxiety Inventory; ability to talk and understand Persian; no need for angiography or surgery in next day after intervention; being oriented to person, place and time Exclusion criteria: Lack of consent ti continue study; experienced cardiac dysrhythmia, pain or dyspnea; death during the study; patients who developed allergy to aroma

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Randomization with table of random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Next to Milad Hospital, Hemmat Highway, Tehran

City

Tehran

Postal code

1449614535

Approval date

2015-06-18, 1394/03/28

Ethics committee reference number

IR.IUMS.REC.1394.26598

Health conditions studied

1

Description of health condition studied

Acute Coronary Syndrom

ICD-10 code

NEC 124.9

ICD-10 code description

Acute ischaemic heart disease, unspecified

Primary outcomes

1

Description

anxiety

Timepoint

30 min before intervention and 30 min after intervention and following tomorow morning at 7 am

Method of measurement

Spielberger State-Trait Anxiety

2

Description

blood pressure

Timepoint

30 min before intervention and 30 min after intervention and each 4 hours until following tomorow morning at 7 am

Method of measurement

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3

Description

pulse

Timepoint

30 min before intervention and 30 min after intervention and each 4 hours until following tomorow morning at 7 am

Method of measurement

Pulse count by the researcher in a minute

4

Description

respiration

Timepoint
30 min before intervention and 30 min after intervention and following tomorow morning at 7 am
Method of measurement
Visit chest going up and down in a minute by researcher

Secondary outcomes

1

Description
-
Timepoint
-
Method of measurement
-

Intervention groups

1

Description
Intervention droup 1:The aroma group , two drops of the blend of Lavender,Roman chamomile and Neroli oils at a ratio of 6:2:0/5 will be shed on pad eye and the patients are asked from a distance of 5cm inhale through 10 deep breaths at 7 pm and the aroma pad will be placed under the patients pillow until the following morning.
Category
Treatment - Other

2

Description
Intervention group 2: placebo group, patients will be received two drops of distilled water on eyepad and the patiens are asked from a distance of 5cm inhale through 10 deep breaths at 7 pm and the aroma pad will be placed under the patients pillow until the following morning.
Category
Placebo

3

Description
Control group : will be received conventional nursing care.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Sajjad Hospital
Full name of responsible person
Raheleh Rahmani
Street address
Valieasr avenue, Shahriar, Tehran
City
Shahriar

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Iran University of Medical Sciences
Full name of responsible person
Seyed Ali Javad Moosavi
Street address
Next to Milad Hospital, Hemmat Highway, Tehran
City
Tehran
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 of Iran 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
Iran University of Medical Sciences-School of Nursing & Midwifery
Full name of responsible person
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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