Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of aromatherapy with valerian and lavender essential oil on vital signs, drug use and headache relief due to nitroglycerin infusion in coronary artery disease

Protocol summary

Study aim

Determining the effect of aromatherapy with lavender and valerian essential oil on vital signs, drug use and relief of headache caused by nitroglycerin infusion in patients with coronary artery disease admitted to the CCU wards of Bu Ali Hospital in Qazvin province.

Design

This process will be performed by one of the ward nurses who is not aware of the research. Informed and written consent will be obtained from all patients who wish to participate in the study. Both groups do not know the type of fragrance used, and instead of naming the fragrance, numbers 1 and 2 are used by someone outside the research team, and the researcher and statistical consultant is not aware of this numbering.

Settings and conduct

Patients are selected and will be divided into three groups. Patients in the experimental group (lavender and valerian group) after complaining of headache, lavender essential oil 1.5% and valerian They will inhale 1.5% with cotton soaked in 3 drops of it that is attached to the collar of their clothes for 30 minutes.In the control group, no intervention will be performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria were: no previous history of nitrate use, no history of allergies, no use of painkillers 6 hours before the intervention, no headache before the intervention, no use of perfume or cologne before or during the intervention, No history of drug addiction According to the patient, no olfactory disorder that affects the sense of smell. Exclusion criteria included withdrawal from the study, headache prior to nitroglycerin infusion, decreased level of consciousness during the study, allergies to essential oils of valerian and lavender or herbal essences during the study.

Intervention groups

Eligible patients are randomly divided into three groups: 1. Lavender, 2. Valerian and 3. Control group.

Main outcome variables

BP; heart beat; Temp;RR; SPO2;pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210516051316N1**
Registration date: **2021-09-18, 1400/06/27**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-18, 1400/06/27**
Update count: **0**

Registration date

2021-09-18, 1400/06/27

Registrant information

Name

Fatemeh Ghapanvari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 3036

Email address

f.ghapanori@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-06, 1400/04/15

Expected recruitment end date

2022-07-06, 1401/04/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effect of aromatherapy with valerian and lavender essential oil on vital signs, drug use and headache relief due to nitroglycerin infusion in coronary artery disease

Public title
The effect of valerian and lavender essential oil on coronary heart disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
No previous history of nitrate use no history of allergies no use of painkillers 6 hours before the intervention no headache before the intervention no use of perfume or cologne before or during the intervention No history of drug addiction according to the patient no olfactory disorder according to the patient
Exclusion criteria:
Withdrawal from the study having a headache before the infusion of nitroglycerin decreased level of consciousness during the study allergies caused by the essential oils of valerian and lavender or herbal essences during the study
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, eligible patients will be divided into three groups: lavender, 2. valerian and 3. control group by random sampling with ball and bag tools. Patients are told that the effect of a scent on them is measured, which is not harmful to them. This process will be performed by one of the ward nurses who is not aware of the research (someone outside the research team). That is, this person numbers the scents and writes the name and number of each scent in an envelope and after completing the analysis to The researcher delivers. Both groups do not know the type of fragrance used and number 1 and 2 are used instead of the name on the fragrance. The researcher and statistical consultant is not aware of this numbering.
Blinding (investigator's opinion)
Triple blinded
Blinding description
Both groups did not know the type of fragrance used, and instead of naming the fragrance, numbers 1 and 2 were used by someone outside the research team, and the researcher was not aware of this numbering; Also, the statistical consultant did not know the names of the fragrances and only the analysis was performed with numbers 1 and 2 and the control group. The appearance of the scents and the packaging and the color and shape of their use are quite similar.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of Qazvin University of Medical Sciences
Street address
Shahid Beheshti Boulevard
City
Qazvin
Province
Qazvin
Postal code
1531534199
Approval date
2019-11-21, 1398/08/30
Ethics committee reference number
IR.QUMS.REC.1398.200

Health conditions studied

1

Description of health condition studied
Coronary artery disease
ICD-10 code
I25.1
ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
blood pressure
Timepoint

30 minutes (before the intervention and 15, 30)

Method of measurement

manometer

2

Description

Drug use following the inhalation of fragrance and its effect on headache The need for narcotics changes based on the visual pain scale.

Timepoint

30 minutes (before the intervention and 15, 30)

Method of measurement

Visual Analogue Scale

3

Description

Heart rate

Timepoint

30 minutes (before the intervention and 15, 30)

Method of measurement

Heart rate monitoring device

4

Description

Temperature

Timepoint

30 minutes (before the intervention and 15, 30)

Method of measurement

Mercury thermometer

5

Description

Respiratory Rate

Timepoint

30 minutes (before the intervention and 15, 30)

Method of measurement

Count the number of breaths per minute based on chest movements while breathing

6

Description

Percentage of blood oxygen saturation

Timepoint

30 minutes (before the intervention and 15, 30)

Method of measurement

pulse oximetry

Secondary outcomes

1

Description

pain

Timepoint

30 minutes (before the intervention and 15, 30)

Method of measurement

Visual Analogue Scale (VAS)

Intervention groups

1

Description

Intervention group: 1. Lavender" Patients of the experimental group (lavender group) After complaining of headache, lavender essential oil 1.5% prepared by Kazerun Agro-industrial Company with cotton soaked in 3 drops of it to the collar Inhaled for 30 minutes, vital signs including blood pressure, heart rate, temperature, and blood oxygen saturation before and after the intervention were measured in three groups. The time period (before the intervention and 15, 30 and 60 minutes after the intervention) was measured using the visual pain scale.

Category

Treatment - Other

2

Description

Intervention group: 2. Valerian "Patients of the experimental group (Valerian group) After complaining of headache, Valerian essential oil 1.5% prepared by Kazerun Agro-industrial Company with cotton soaked in 3 drops of it to the collar Inhaled for 30 minutes, vital signs including blood pressure, heart rate, temperature, and blood oxygen saturation before and after the intervention were measured in three groups. The time period (before the intervention and 15, 30 and 60 minutes after the intervention) was measured using the visual pain scale.

Category

Treatment - Other

3

Description

"Control group" In the control group, no intervention was performed and only the usual methods of pain control performed in the ward were performed in these patients. Vital signs including blood pressure, heart rate, temperature, blood oxygen saturation before and after the intervention were also measured in three groups. The severity of patients' headache in 4 time periods (before the intervention and 15, 30 and 60 minutes after the intervention) was measured using the visual pain scale.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

CCU Wards of Bu Ali Hospital in Qazvin province

Full name of responsible person

Leili Yekefallah

Street address

Department of Nursing, Social Determinants of Health Research Center, School of Nursing & Midwifery, Qazvin University of Medical Sciences, Qazvin, Iran

City
Qazvin

Province
Qazvin

Postal code
3419915315

Phone
+98 28 3333 8034

Fax
+98 28 3335 5162

Email
leili_fallah@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Seyed Mahdi Mirhashemi

Street address
Qazvin - Shahid Beheshti Boulevard, Subsidiary Moedat

City
Qazvin

Province
Qazvin

Postal code
13911/34156

Phone
+98 28 3333 8034

Fax
+98 28 3335 5162

Email
research.dpt@qums.ac.ir

Grant name
Vice Chancellor for Research, Qazvin University of Medical Sciences

Grant code / Reference number

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

Title of funding source
Qazvin University of Medical Sciences

Proportion provided by this source
10

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
Qazvin University of Medical Sciences

Full name of responsible person
Leili Yekefallah

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Health Promotion

Street address
Department of Nursing, Social Determinants of Health Research Center, School of Nursing & Midwifery, Qazvin University of Medical Sciences, Qazvin, Iran

City
Qazvin

Province
Qazvin

Postal code
3419915315

Phone
+98 28 3333 8034

Fax
+98 28 3335 5162

Email
leili_fallah@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Fatemeh Ghapanvari

Position
3. Mcs Student of Critcal Care Nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Shahid Bahonar Boulevard - Qazvin University of Medical Sciences, Qazvin, Iran

City
Qazvin

Province
Qazvin

Postal code
3419915315

Phone
+98 28 3333 8034

Fax
+98 28 3335 5162

Email
fatemehghapanvari89@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Kamal Ebrahimi

Position
Mcs Student of Psychiatric Nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
Shahid Bahonar Boulevard -Qazvin University of Medical Sciences, Qazvin, Iran

City
Qazvin

Province
Qazvin

Postal code
3419915315

Phone
+98 28 3333 8034

Fax
+98 28 3335 5162

Email
Kamal.ebrahimi95@gmail.com

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
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Details of the file are written in the text of the article

When the data will become available and for how long
After conducting research and accepting the article is visible.

To whom data/document is available
Article readers

Under which criteria data/document could be used
For the use of students and health centers and under the conditions of reading the article published

From where data/document is obtainable
Qazvin University of Medical Sciences

What processes are involved for a request to access data/document
First, the irct code is taken and sampling is done and the data is analyzed and then the article is registered

Comments
Not applicable