Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison the effect of aromatherapy with lavender and rose essence on the prevention headache due to Nitroglycerine infusion in patient admitted to cardiac care unite

Protocol summary

Study aim
Comparison the Effect of Lavender and rose essence on the prevention headache due to Nitroglycerine in Patients admitted to ccu

Design
A randomized controlled clinical trial with parallel and groups, not blinded, was randomized

Settings and conduct
in the intervention group of lavender and rose, at the same time as the infusion of nitroglycerin, aromatherapy with cotton soaked in 3 drops of lavender and rose will be performed for half an hour.No aromatherapy will be used in the control group.Using the VAS pain scale, the severity and frequency of headaches will be measured at 15, 30, 60, 90 minutes after aromatherapy. In case of pain in each group, routine treatment of headache, 325 mg acetaminophen tablets will be used and will be recorded in the patient questionnaire.The instruments used in this study are Patient Profile Questionnaire and VAS Pain Scale Questionnaire.Study population: Patients admitted to the cardiac care unit of Hospital Allameh Bohlool Gonabadi

Participants/Inclusion and exclusion criteria
Willingness to participate in the study;Age range from 70to30 years;Awareness of time and place and people;Having a doctor's order to get infused nitroglycerin;No headache before infusion of nitroglycerin;No history of allergies to any herbal medicine;No olfactory disorder and colds and nasal congestion;No analgesics before the start of infusion nitroglycerin;No history of respiratory problems;No pregnancy;No history of drug addiction

Intervention groups
In the intervention group of lavender and rose, at the same time as the infusion of nitroglycerin, aromatherapy with cotton soaked in 3 drops of lavender and rose will be performed for half an hour.No aromatherapy will be used in the control group.

Main outcome variables
Aromatherapy; Headache severity; Headache incidence; Age; Gender Education; Height; Weight; Marriage; History of hospitalization; Incidence of angina

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190715044221N1**
Registration date: **2019-10-16, 1398/07/24**
Registration timing: **prospective**

Last update: **2019-10-16, 1398/07/24**
Update count: **0**

Registration date
2019-10-16, 1398/07/24

Registrant information

Name
Fereshte Jalili

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 5722 0604

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-23, 1398/08/01

Expected recruitment end date
2019-12-22, 1398/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison the effect of aromatherapy with lavender and rose essence on the prevention headache due to Nitroglycerine infusion in patient admitted to cardiac care unite

Public title
Comparison the effect of aromatherapy with lavender and rose essence on the prevention headache due to Nitroglycerine infusion
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Age range from 30to 70 years Awareness of time and place and people Having a doctor's order to get infused nitroglycerin No headache before infusion of Nitroglycerin No history of allergies to any herbal medicin No olfactory disorder and colds and nasal congestion No analgesics before infusion of Nitroglycerin No history of respiratory problems No pregnancy Do not use perfume or cologne during aromatherapy No history of drug addiction
Exclusion criteria:
Not willing to continue cooperation Allergic to lavender and roses during the study
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the research units will be selected by available method and will be randomly assigned by permutation blocks with 3 blocks in three groups (Lavender and Rose and control). The 6 possible modes for the blocks are as follows: ABC, BAC, CAB, ACB, BCA, CBA. Each block will be assigned a number between one and six, and will then be assigned to the control group (A), lavender (B), and rose (C) based on the block corresponding to the number selected. This will continue until the sample size (14 blocks) is complete. In this study, the randomization tool is a random number table.
Blinding (investigator's opinion)
Single blinded
Blinding description
Clinical participants and caregivers, are not aware of the intervention type.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Gonabad University of Medical sciences
Street address
Santo Road
City
gonabad
Province
Razavi Khorasan
Postal code
9691797852
Approval date
2019-05-13, 1398/02/23
Ethics committee reference number
IR.GMU.REC.1398.061

Health conditions studied

1

Description of health condition studied
Headache in heart patients
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Headache caused by infusion of nitroglycerin
Timepoint
Frequency and severity of headache 15, 30, 60 and 90 minutes after nitroglycerin infusion
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Frequency and severity of angina
Timepoint

15, 30, 60 and 90 minutes after starting aromatherapy

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group: Lavender group: In this group, at the same time as the infusion of nitroglycerin, aromatherapy with cotton impregnated with three drops of 20% lavender essential oil will be performed for half an hour.

Category

Prevention

2

Description

Intervention group:Rose group: In this group, at the same time as the infusion of nitroglycerin, the aromatherapy with cotton soaked in three drops of rose essential oil 40% made by Gorgan Company will take half an hour.

Category

Prevention

3

Description

Control group: No perfume will be given at the same time as nitroglycerin infusion is started.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Bohlool hospital

Full name of responsible person
Kokab basiri moghadam

Street address
Parastar Blvd,Bohlool hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Gonabad University of Medical Sciences

Full name of responsible person
SHahla KHosravan

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Grant name

Grant code / Reference number

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

Title of funding source
Gonabad 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
Gonabad University of Medical Sciences

Full name of responsible person
fereshte jalili

Position
nurse

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

kokab basiri moghadam

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Nursing Graduate Student

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Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available