

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 51 5722 0604

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f.jalili1826@gmail.com

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

AgeFrom **30 years** old to **70 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample sizeTarget 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

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Santo Road

City

gonabad

Province

Razavi Khorasan

Postal code

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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

Bohloul hospital

Full name of responsible person

Kokab basiri moghadam

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Parastar Blvd,Bohloul 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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kokab basiri moghadam

Position

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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