

# 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

##### Email address

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

**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**

Bohloul hospital

###### **Full name of responsible person**

Kokab basiri moghadam

###### **Street address**

Parastar Blvd,Bohloul hospital

###### **City**

Gonabad

###### **Province**

Razavi Khorasan

###### **Postal code**

9691797852

###### **Phone**

+98 51 5723 6833

###### **Fax**

+98 51 5723 6160

###### **Email**

f.jalili1826@gmail.com

###### **Web page address**

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Gonabad University of Medical Sciences

###### **Full name of responsible person**

SHahla KHosravan

###### **Street address**

sento road

###### **City**

gonabad

###### **Province**

Razavi Khorasan

###### **Postal code**

9691797852

###### **Phone**

+98 51 5722 3028

###### **Email**

f.jalili1826@gmail.com

##### **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

###### **Street address**

Nurse Blvd, Bohloul hospital

###### **City**

gonabad

###### **Province**

Razavi Khorasan

###### **Postal code**

9691797852

###### **Phone**

+98 51 5723 6833

**Email**

f.jalili1826@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

kokab basiri moghadam

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursery

**Street address**

sento road,Gonabad university of medical sciences

**City**

gonabad

**Province**

Razavi Khorasan

**Postal code**

9691797852

**Phone**

+98 51 5722 3028

**Email**

k.basiri@gmu.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Gonabad University of Medical Sciences

**Full name of responsible person**

fereshte jalili

**Position**

Nursing Graduate Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

parastar Blvd,Bohloul hospital

**City**

gonabad

**Province**

Razavi Khorasan

**Postal code**

96917-97852

**Phone**

+98 51 5723 6833

**Email**

f.jalili1826@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**

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