

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison the effect of aromatherapy with Lavender essential oil versus Acetaminophen tablet on Nitroglycerin-induced headache and comfort in the patients with angina pectoris in Cardiac Care Units

Protocol summary

Study aim

Comparison the effect of aromatherapy with Lavender essential oil versus Acetaminophen tablet on Nitroglycerin-induced headache and comfort in the patients with angina pectoris in Cardiac Care Units

Design

Clinical trial with randomized control group

Settings and conduct

Cardiac Care Units affiliated to Hamedan University of Medical Sciences in three groups (Acetaminophen, Lavender essential oil and control) Patients' headache was assessed in all three groups with the standard scale of pain assessment (VAS) Evaluating the comfort of patients in all three groups was the standard scale of comfort assessment (VAS)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 30-60 years; receiving Nitroglycerin infusion for the first time; receiving acetaminophen PRN; Not having a history of a migraine or a chronic headache Exclusion criteria: Hypotension; Drug hypersensitivity

Intervention groups

1. The Acetaminophen group: Oral Acetaminophen (500 mg of a product from a prestigious company) that is having order in the form of PRN, which is given to the patient 15 minutes before infusion of Nitroglycerin. 2. Lavender essential oil group: In this group, cotton dusted with 3 drops of 2% non-fatty lavender essential oil prepared from a prestigious company, 15 minutes before the onset of nitroglycerin infusion, is attached to the collar and is Inhaled by the patient. 3. Control group: This group of patients will receive only common care, and Acetaminophen and Lavender essential oil will not be given as a preventive intervention.

Main outcome variables

Prevention of Nitroglycerin headaches

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180927041157N1**

Registration date: **2018-11-10, 1397/08/19**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-10, 1397/08/19**

Update count: **0**

Registration date

2018-11-10, 1397/08/19

Registrant information

Name

Roghayeh Ezati-Soleaman

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3262 1123

Email address

r.ezati@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of aromatherapy with Lavender essential oil versus Acetaminophen tablet on Nitroglycerin-induced headache and comfort in the patients with angina pectoris in Cardiac Care Units

Public title

Comparison effect of Lavender and Acetaminophen on Nitroglycerin-induced headache

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Receiving Nitroglycerin infusion for the first time
Receiving Acetaminophen PRN
Not having a history of sublingual Nitroglycerin use
Not having a history of migraine or chronic headaches
No sensitivity to Acetaminophen
No sensitivity to medicinal Plants
Lack of olfactory disorders
Ability to swallow
Ability to speak

Exclusion criteria:

Hypotension
Drug susceptibility

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be selected by simple sampling method and in the form of permutable blocks ABC-ACB -BCA -BAC - CAB -CAB is randomly assigned to three groups (Acetaminophen, Lavender essential oil and control).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hamedan University of Medical Sciences

Street address

Besat Hospital

City

Hamedan

Province

Hamadan

Postal code

6514887467

Approval date

2018-09-01, 1397/06/10

Ethics committee reference number

IR.UMSHA.REC.1397.409

Health conditions studied

1

Description of health condition studied

Angina

ICD-10 code

I20-I25

ICD-10 code description

Ischaemic heart diseases

Primary outcomes

1

Description

Pain scale by VAS scale

Timepoint

The evaluation of the patient's headache at 5, 10, 15, and 60 minutes after the onset of Nitroglycerine infusion

Method of measurement

The evaluation of the patient's headache in three groups (Acetaminophen, Lavender essential oil and control) at 5, 10, 15, and 60 minutes after the onset of Nitroglycerine infusion will be measured.

2

Description

Comfort scale by VAS scale

Timepoint

The evaluation of the patient's comfort 15 minutes before infusion and at 60 minutes after initiation of nitroglycerin infusion

Method of measurement

The evaluation of the patient's comfort (VAS) 15 minutes before infusion and at 60 minutes after initiation of nitroglycerin infusion in three groups (acetaminophen, lavender essential oil and control) will be measured.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group: The Acetaminophen Group: Oral Acetaminophen (500 mg) of the Alborz Drug Company is prescribed by the physician as needed (PRN), which is

given to a patient 15 minutes prior to the onset of nitroglycerin infusion.

Category

Prevention

2

Description

Intervention group: Lavender group: In this group, cotton dusted with 3 drops of 2% non-fatty lavender essential oil prepared from, Tabib Medical Company 15 minutes before the onset of nitroglycerin infusion, is attached to the collar and will be washed by the patient.

Category

Prevention

3

Description

Control group: Only common care will be taken to treat headache caused by nitroglycerin infusion.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital and Farshchian heart hospital

Full name of responsible person

Roghayeh Ezati-soleaman

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Research and Technology Vice-Chancellor

Street address

In front of Mardom Park

City

Hamadan

Province

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65178-38678

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internationalaffairs@umsha.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Arezo Karamporian

Position

Teacher

Latest degree

Master

Other areas of specialty/work

Nursery

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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

Yes - There is a plan to make this available

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

The total data after unidentifiable participants can be shared.

When the data will become available and for how long

After the end of the study

To whom data/document is available

Researchers working in academic centers

Under which criteria data/document could be used

For the treatment of patients

From where data/document is obtainable

Email address

What processes are involved for a request to access data/document

Requesting information is possible through the author's email at the end of the study.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Roghayeh ezati soleiman

Position

Nursing student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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