Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Inhalated 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

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Iran (Islamic Republic of)

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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

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Hamadan

Province

Hamadan

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65178-38678

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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

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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Person responsible for updating data

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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