Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial of study the effect of aromatherapy with Lavandula oil on pain, anxiety and hemodynamic parameters of patients after coronary artery bypass grafting surgery

Protocol summary

Summary

Aim: determine the effect of aromatherapy with Lavandula oil on pain, anxiety and hemodynamic parameters of patients after coronary artery bypass grafting surgery Study design: randomized, double-blind, placebo-controlled, one center Inclusion criteria: without history of drugs affecting on neurological system; without smell disorders; without history of pulmonary diseases, hepatitis, diabetes, chronic headaches and thyroid diseases; without history of drugs abuse; orientation; without history of sensitivity to plants, especially Lavandula; without history of aromatherapy; duration of intubation in the range of 6 to 8 hours; not to use analgesic and antianxiety during 3 hours before starting of the study; having a systolic blood pressure 95 mm Hg and upper than. Exclusion criteria: any sudden onset of severe changes in vital signs and droplet the systolic blood pressure lower than 95 mm Hg at each stage of the research. Sample size: 98 cases Study population: patients after coronary artery bypass grafting surgery admitted in cardiac surgery ward. Intervention: in the intervention group 5 drops of Lavandula oil 100 % and in the placebo group 5 drops of distilled water will rub on the upper lips of patient and would be inhaled in 30 minutes by the patient. Pain intensity by using Visual Analoge Scale, the anxiety level by using part of anxiety of the hospital anxiety and depression scale and hemodynamic parameters will be measured before and after each intervention. Time: from the early day of admitted patients in cardiac surgery ward for three consecutive days. The primary outcome: relief of pain, anxiety and hemodynamic parameters changes after coronary artery bypass grafting surgery

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014102119617N1**
Registration date: **2014-12-17, 1393/09/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-12-17, 1393/09/26

Registrant information

Name

Ezzat Paryad

Name of organization / entity

Guilan University of Medical Sciences, Shahid Beheshti Nursing and Midwifery Faculty

Country

Iran (Islamic Republic of)

Phone

+98 13 3355 5056

Email address

e_paryad@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Clinical trial of study the effect of aromatherapy with Lavandula oil on pain, anxiety and hemodynamic parameters of patients after coronary artery bypass grafting surgery

Public title
The effect of aromatherapy with Lavandula oil on pain, anxiety and hemodynamic parameters

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: admitted for coronary artery bypass surgery in cardiac surgery ward at Dr. Heshmat Educational and Medical Center in Rasht; patients over 18 years old; without history of drugs affecting on neurological system based on documents; without smell and visual disorders based on commenting of patient; without history of pulmonary diseases, hepatitis, diabetes, chronic headaches, migraines and psychological disorder; without history thyroid diseases (based on documents); without history of cardiac surgery; tendency to collaboration; without history of drugs abuse, smoking and alcohol (based on documents); orientation; without history of allergies, contact dermatitis and sensitivity to plants, especially Lavandula and cosmetic fragrances; without acute diseases; without history of aromatherapy based on documents; bedridden in Intensive Care Unit under 72 hours; duration of intubation in the range of 6 to 8 hours in the Intensive Care Unit based on documents; not to use analgesic, antianxiety drugs, sedative and narcotics during 3 hours before starting of the study and having a systolic blood pressure of 95 mm Hg and upper than. Exclusion criteria: any sudden onset of severe changes in vital signs; onset of respiratory allergy signs and having a systolic blood pressure lower than 95 mm Hg at each stage of the research.

Age
From **18 years** old to **139 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **98**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The ethics committee of assistance of research of Guilan University of Medical Sciences

Street address
Shahid Beheshti Nursing and Midwifery Faculty, Guilan University of Medical Sciences, Highway of Shahid Beheshti, Student Avenue

City
Rasht

Postal code
41469-39841

Approval date
2014-11-17, 1393/08/26

Ethics committee reference number
2930382805

Health conditions studied

1

Description of health condition studied
Lavender oil aromatherapy associated with pain, anxiety and hemodynamic parameters in patients after coronary artery bypass grafting surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain

Timepoint
Before the intervention and half hour after the intervention every 24 hours for three consecutive days

Method of measurement
Visual Analoge Scale

2

Description
Anxiety

Timepoint
Before the intervention and half hour after the intervention every 24 hours for three consecutive days

Method of measurement
Section of anxiety of the Hospital Anxiety and Depression Scale (HADS)

3

Description

Diastolic and systolic blood pressure

Timepoint

Before the intervention and half hour after the intervention every 24 hours for three consecutive days

Method of measurement

By using a mercury sphygmomanometer based on mmHg

4

Description

Pulse

Timepoint

Before the intervention and half hour after the intervention every 24 hours for three consecutive days

Method of measurement

Based on the number of pulses in a minute

5

Description

Respiration

Timepoint

Before the intervention and half hour after the intervention every 24 hours for three consecutive days

Method of measurement

Based on the number of breaths in a minute

Secondary outcomes

empty

Intervention groups

1

Description

In the intervention group 5 drops of Lavandula oil 100% will rub on the upper lips of patient (the distance between the nose and lips) and would be inhaled in 30 minutes by the patient. Intervention will be done every 24 hours for three consecutive days after discharge from the Intensive Care Unit.

Category

Other

2

Description

In the placebo group 5 drops of distilled water will rub on the upper lips of patient (the distance between the nose and lips) and would be inhaled in 30 minutes by the patient. Intervention will be done every 24 hours for three consecutive days after discharge from the Intensive Care Unit.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Heshmat Educational and Medical Center Hospital

Full name of responsible person

Ezzat Paryad

Street address

Dr. Heshmat Educational and Medical Center Hospital, 15 Khordad Avenue, next to the Management and Planning Organization of Guilan

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Atefeh Ghanbari

Street address

Shahid Beheshti Nursing and Midwifery Faculty, Guilan University of Medical Sciences, Highway of Shahid Beheshti, Student Avenue

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Guilan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences, Shahid Beheshti Nursing and Midwifery Faculty

Full name of responsible person

Ezzat Paryad

Position

M.Sc, Faculty member of Guilan University of Medical Sciences

Other areas of specialty/work

Street address

Shahid Beheshti Nursing and Midwifery Faculty,

Guilan University of Medical Sciences, Highway of Shahid Beheshti, Student Avenue

City
Rasht

Postal code
41469-39841

Phone
+98 13 3355 5056

Fax
+98 13 3355 0097

Email
e_paryad@gums.ac.ir; samaneh.ebrahimi8@gmail.com

Web page address
www.gums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Guilan University of Medical Sciences, Shahid Beheshti Nursing and Midwifery Faculty

Full name of responsible person
Ezzat Paryad

Position
M.Sc

Other areas of specialty/work

Street address
Shahid Beheshti Nursing and Midwifery Faculty, Guilan University of Medical Sciences, Highway of Shahid Beheshti, Student Avenue

City
Rasht

Postal code
41469-39841

Phone
+98 13 3355 5056

Fax
+98 13 3355 0097

Email
e_paryad@gums.ac.ir; samaneh.ebrahimi8@gmail.com

Web page address
www.gums.ac.ir

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty