Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Massage and Aromatherapy with Passionate Flower Scent on Pain Intensity and Sleep Quality of Patients Following Coronary Artery Cardiac Surgery in the ICU

Protocol summary

Study aim

The effect of massage and aromatherapy with passionate flower scent on pain intensity and sleep quality of patients following coronary artery cardiac surgery in the ICU.

Design

The study is design as a randomised, controlled, parallel group trial with single blinded outcome assessment. Randomisation will centralised based on simple randomization method using random digits table.

Settings and conduct

Sixty patients undergoing coronary artery cardiac surgery are randomly divided and evaluated into three intervention and control groups (n=30) in Isafahan Shahid Chamran hospital. Intervention during 4 sessions in the second and third days following surgery in the ICU and then 2 days after transferring the patients to the ward in the final hours of day, at least 4 hours after prescribed opioid analgesic, will be performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria are patients in age group 18 to 45 years, the patients who are able to speak and self-report, awareness of time and place, systolic blood pressure between 90 to 160 mmHg, mean arterial pressure above 60 mmHg, heart rate between 60 to 100 beats per minute and pain score above 3 according to VAS; The exclusion criteria are patients with olfactory disorder, skin allergy to Passionate Flower extract, chronic musculoskeletal pain, sensory and motor problems and history of mental disorders

Intervention groups

In intervention group, four sessions of Swedish Massage Surface Stroke Technique along with 2 ml of Passionate Flower extract will be performed for 20 minutes on feet, hands, shoulders and lumbar region. In control group, massage without Passionate Flower extract will be performed.

Main outcome variables

The pain intensity before and 30 minutes after massage, sleep quality score in the morning after intervention and the amount of prescribed opioid analgesic during intervention are measured.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191026045249N1**
Registration date: **2020-01-20, 1398/10/30**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-20, 1398/10/30**
Update count: **0**

Registration date

2020-01-20, 1398/10/30

Registrant information

Name

Nasrin Mousa Hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 5910 7500

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Massage and Aromatherapy with Passionate Flower Scent on Pain Intensity and Sleep Quality of Patients Following Coronary Artery Cardiac Surgery in the ICU

Public title
The Effect of Massage and Aromatherapy with Passionate Flower Scent on Pain Intensity and Sleep Quality of Patients in the ICU
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age group 18 to 45 years The patients who are able to speak and self-report Awareness of time and place Systolic blood pressure between 90 to 160 mmHg Mean arterial pressure above 60 mmHg Heart rate between 60 to 100 beats per minute Pain score above 3 according to the visual analogue scale (VAS)
Exclusion criteria:
Patients with olfactory disorder Patients with skin allergy to Passionate Flower extract Patients with chronic musculoskeletal pain Patients with sensory and motor problems Patients with history of mental disorder
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals are randomly divided into two groups based on simple randomization method using random digits table. In this method, a collection of non-template numbers is randomly generated and arranged as a table. Even numbers for the intervention group and the odd numbers for the control group are considered. According to the number of patients, they are randomly assigned to one of the intervention or control groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
Researchers responsible for data collection and analyses will blinded to the groups allocation for preventing personal viewpoint.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Deputy of Research, Isfahan University of Medical Sciences, Hezar Jerib Ave.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2019-08-18, 1398/05/27
Ethics committee reference number
IR.MUI.RESEARCH.REC.1398.295

Health conditions studied

1

Description of health condition studied
Coronary artery cardiac disease
ICD-10 code
I25.9
ICD-10 code description
Chronic ischemic heart disease, unspecified

Primary outcomes

1

Description
Pain intensity
Timepoint
Before and 30 minutes after massage
Method of measurement
Visual analogue scale (VAS)

2

Description
Sleep quality score
Timepoint
The morning after the intervention
Method of measurement
Verran and Snyder-Halpern Sleep Scale (VSH sleep scale)

3

Description
The amount of prescribed opioid analgesic medication
Timepoint
During the intervention
Method of measurement
Total receiving dose of opioid analgesic medication

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Four sessions of Swedish Massage Surface Stroke Technique along with 2 ml of Passionate Flower extract will be performed for 20 minutes on feet, hands, shoulders and lumbar region.
Category
Rehabilitation

2

Description
Control group: Four sessions of Swedish Massage Surface Stroke Technique without Passionate Flower extract will be performed for 20 minutes on feet, hands, shoulders and lumbar region.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Chamran hospital, Isfahan University of Medical Sciences
Full name of responsible person
Ahmad Reza Yazdan Nik
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Shahid Chamran hospital, third Moshtagh Ave., Bozorgmehr square
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Sponsors / Funding sources

1

Sponsor
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Nasrin Mousa Hoseini
Position
Student undertaking a master's degree
Latest degree
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Person responsible for updating data

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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable