

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 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 be 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.

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Isfahan

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.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Anooshe Zargar, PhD

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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

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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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