Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the effect of reflexology massage of aromatic and non-aromatic oil on the pain of patients after coronary artery bypass graft surgery

Protocol summary

Study aim
Comparison of the effect of reflexology massage of aromatic and non-aromatic oil on the pain of patients

Design
Clinical trials with control group,with parallel groups, blind, randomized

Settings and conduct
This clinical trial study was conducted as double blind. Patients were randomly refereed to Rasht Hospital were assigned by randomized block into three subgroups: aromatherapy, scented oil, and control group. Subjects were then treated with almond oil for 20 minutes on the floor left foot performs. In the aromatic oil group, the patient's left lower limb is massaged using a mixture of almond oil and lavender oil for 20 minutes. In the control group, the left foot of the patient is given massage for 20 minutes. Evaluation of pain at 6, 12, and 24 minutes after intervention in the previous stage and 30 minutes later, the intervention was examined. In order to do double blinding in the study, the interval of massage was increased to 30 minutes after the intervention, and the amount of lavender oil scent was not known and the findings of the study group were not known.

Participants/Inclusion and exclusion criteria
Entry criteria: complete awareness; patient satisfaction to participate in the study. Exit criteria: unwillingness to participate and continue cooperation in the study; lack of full vigilance.

Intervention groups
In the 6th hour after the operation,the researcher examines the amount of pain before the intervention.Then,the left foot practitioner will massage the almond oil for 20 minutes.In the aromatic oil group, the patient's left lower limb using a mixture of almond oil and lavender oil for 20 minutes Massage is given. In the control group, the left foot of the patients is given a dry massage for 20 minutes.The rest of the room conditions will be the same for the three groups.This procedure will also be repeated at 12 and 24 hours postoperatively.

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181126041762N2**
Registration date: **2019-05-16, 1398/02/26**
Registration timing: **registered_while_recruiting**

Last update: **2019-05-16, 1398/02/26**
Update count: **0**

Registration date
2019-05-16, 1398/02/26

Registrant information

Name
Samere Rasouli

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 13 3467 2372

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-04, 1398/01/15

Expected recruitment end date
2019-07-22, 1398/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of reflexology massage of aromatic and non-aromatic oil on the pain of patients after coronary artery bypass graft surgery

Public title

Comparison of the effect of foot massage on postoperative pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Complete vigilance Patient Satisfaction to Participate in the Study Heart surgery for the first time Elective Heart Surgery No use of nerve and respiratory drugs Hemodynamic stability Having a sense of smell and no hearing loss or vision

Exclusion criteria:

Unwillingness to participate and continue cooperation in the study Not having full vigilance Lack of sense of smell, hearing loss or an inability to communicate Intooth more than 6 hours later The history of chronic pain Having a fracture, an infective wound on the left foot Drug Addiction Need to re-intubate or re-arrange the heart

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned into three groups: massage therapy and massage with non-aromatic oil and non-oil control group. Each block is executed in a variety of possible states of the letters AABBCC and then by random selection for each block to complete the sample size. In the study, they are assigned to each of the three groups that are collected in collaboration with the head nurse. We will record the type of intervention with a four-digit code in a suitable position and refer the eligible patients from Nos. 1 to 108 to the envelope and the four-digit pre-prepared intervention in the appropriate container inside the envelope. The evaluator is collecting the data in the form of data collection, with the four-digit code included, but not from the intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Data will be collected in order to blind this study in collaboration with the head nurse. We will record the type of intervention with a four-digit code in a suitable position and refer the eligible patients from Nos. 1 to 108 to the envelope and the four-digit pre-prepared intervention in the appropriate container inside the envelope. The evaluator is collecting data in the form of data collection, with the four-digit code mentioned, but not from the intervention group. The masseur and pain assessor are separate. Also, the massage interval to the next assessment increases the intervention for 30 minutes, to reduce the amount of lavender oil aroma, and after 30 minutes the amount of pain is assessed using a visual analogue scale. This procedure is performed at 12 o'clock And the 24th post-operative is also repeated. On this basis, the evaluator is not aware of the status of the groups. The masseur will also provide intervention for separate and unconnected patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mazandaran University of Medical Sciences

Street address

Field Teacher, Student Research Assistant

City

Sari

Province

Mazandaran

Postal code

44641-55343

Approval date

2019-05-01, 1398/02/11

Ethics committee reference number

IR.MAZUMS.REC.1398.4632

Health conditions studied

1

Description of health condition studied

pain

ICD-10 code

R52

ICD-10 code description

Pain, unspecified

Primary outcomes

1

Description
Pain
Timepoint
Measurement of pain before and after the intervention and after the intervention at 6,12 and 24 hours after surgery
Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: After 6 hours of operation, and after the advancement of the patient, the patient is asked to examine the patient. Prior to massaging, the researcher will examine the pain level using a standardized-neurological scale. The researcher then traces the curtains around the patient and minimizes the external sounds. The researcher next to the patient was sitting on the chair and sitting on the left leg of the feet using almond oil for 1 minute, and for 20 minutes, in addition to relaxing exercises on the foot, massage of the foot of the foot is done on the entire left foot. Then the amount of pain again This intervention is in hours 12 and 24 hours after surgery will be repeated.
Category
Prevention

2

Description
Second intervention group: After 6 hours of operation, and after the advancement of the patient, the patient is asked for treatment. Before applying for massage, the pain is assessed by the researcher using the standard-reporting scale. Next, the researcher draws the curtains around the patient and minimizes the external sounds. Then the researcher next to the patient is seated on the chair and the left leg of the patient using a mixture of almond oil and lavender oil for 1 minute, and for 20 minutes, in addition to relaxing exercises on the foot, massaging of the foot of the foot is done on the entire left foot of the foot. Then the amount The pain is re-examined This intervention at 12 and 24 hours after surgery will be repeated.
Category
Prevention

3

Description
Control group: After 6 hours of operation, and after the advancement of the patient, the patient is asked for treatment. Before exercising, the pain is assessed by the researcher using the standard-obsessive scale. The researcher then draws the curtains around the patient and minimizes the external sounds. The researcher next to the patient was sitting on the sitting chair and the left leg of the patient without using any natural products, for 20 minutes, dry massage, and relaxing exercises on the foot, massage of the foot of the foot on the entire left foot of the leg. Then the amount of pain again This intervention is at 12 o'clock Will be repeated 24 hours after surgery.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Dr. Heshmat Rasht Hospital Research Center
Full name of responsible person
Heydar Dadkhah
Street address
15 Khordad
City
Rasht
Province
Guilan
Postal code
4464155343
Phone
+98 13 3366 9064
Fax
+98 13 3366 8718
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
Full name of responsible person
Ibrahim Nassiri
Street address
Valiasr Street
City
Sari
Province
Mazandaran
Postal code
4815733971
Phone
+98 11 3304 4000
Fax
+98 11 3336 2569
Email
rezafm2002@gmail.com
Grant name

Grant code / Reference number

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

Title of funding source
Sari 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
Mazandaran University of Medical Sciences

Full name of responsible person
Samere Rasouli

Position
Master's degree student operating room

Latest degree
Bachelor

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)
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
Undecided - It is not yet known if there will be a plan to make this available

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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available