Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

A comparative study of the effects of rose water aromatherapy and lavender aromatherapy on the intensity of pain and fatigue of colorectal cancer patients undergoing chemotherapy

Protocol summary

Study aim

Comparison of the effect of Rose Aromatherapy with Lavender Aromatherapy on the intensity of pain and fatigue of colorectal cancer patients undergoing chemotherapy

Design

It is a randomized cross-over clinical trial that without blinding and randomly using a block method of four, people referring to the above medical centers are equally divided into two test groups A (32 people) and B (32 people)

Settings and conduct

The above project is carried out in Bahar (Shahroud city) and Kausar (Semnan city) hospitals. Aromatherapy will be performed individually by the researcher in separate rooms for the patient.

Participants/Inclusion and exclusion criteria

People with colorectal cancer aged between 18 and 70 years, who are natives of Semnan province and have referred to Kausar hospitals in Semnan city and Bahar hospitals in Shahrood city to receive their first to fifth chemotherapy, were considered as inclusion criteria, and people Those who do not want to participate in the study and are other than the stated cases are considered as the exit criteria.

Intervention groups

First, the mentioned questionnaires will be completed for the people who have the conditions to enter the study. In the following, aromatherapy with rose water for group A patients and aromatherapy with lavender for group B patients will be performed during a patient's chemotherapy session. In the following, the above-mentioned questionnaires will be completed for patients with time intervals of half an hour, one hour and four hours from the start of aromatherapy. Then the intervention is washed out for a week to eliminate the effects of aromatherapy. After that, it will be done for patients in group A (inhalation aromatherapy with lavender) and for patients in group B (inhalation aromatherapy with rose water). Again, the above questionnaires will be completed in the same way as before.

Main outcome variables

Pain, Fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200926048842N4**
Registration date: **2023-07-08, 1402/04/17**
Registration timing: **prospective**

Last update: **2023-07-08, 1402/04/17**
Update count: **0**

Registration date

2023-07-08, 1402/04/17

Registrant information

Name

Sajad Salehipour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-11, 1402/04/20

Expected recruitment end date
2023-10-12, 1402/07/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of the effects of rose water aromatherapy and lavender aromatherapy on the intensity of pain and fatigue of colorectal cancer patients undergoing chemotherapy

Public title
Effect of rose and lavender aromatherapy on pain intensity and treatment of colorectal cancer under chemotherapy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Insensitivity to plants and their extracts according to the person's previous history Colorectal cancer has been definitively diagnosed by a hematologist and oncologist. Undergoing the first cycle of chemotherapy up to a maximum of the fifth cycle of chemotherapy Having a pain intensity score of at least 3 based on the questionnaire (VAS) No smoking, drugs and alcohol Not suffering from other known chronic diseases such as heart-pulmonary diseases, blood pressure and diabetes Not using perfume or cologne before or during the intervention Not having an olfactory disorder and also having a cold and nasal congestion that should affect the sense of smell Absence of mental disorders Not receiving natural painkillers 3 hours before the start or during the intervention Having a history of surgery in less than 3 months Having hemoglobin of at least 8gr/dl
Exclusion criteria:
Use of other pain relief methods during the study Refusal to continue participating in the study The patient's lack of awareness colorectal cancer Decreased level of alertness while studying Occurrence of skin and eye allergies during study The occurrence of severe physical complications caused by the disease death of the patient suffering from diseases characterized by fatigue (multiple sclerosis, fibromyalgia, AIDS, joint rheumatism) Presence of perceptual disorders related to smell (olfactory hallucinations)
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be done by the available method. Every patient with colorectal cancer referring to Kausar (Semnan city) and Bahar (Shahroud city) hospitals who meets the inclusion criteria should be included in the study. Then the selected patients are cross-divided into two groups (A, B). In this way, first, envelopes with group names are prepared for the total number of study subjects and randomly arranged and selected by reference and selection of individuals, one of the cards will be identified, which will determine the individual's group. Was. According to random sampling, the research samples will have an equal chance to be selected in two groups.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Semnan University of Medical Sciences
Street address
Headquarters of Semnan University of Medical Sciences and Health Services, Basij Blvd
City
Semnan
Province
Semnan
Postal code
3514799442
Approval date
2023-06-26, 1402/04/05
Ethics committee reference number
R.SEMUMS.REC.1402.065

Health conditions studied

1

Description of health condition studied
Colorectal cancer
ICD-10 code
C19
ICD-10 code description
Malignant neoplasm of rectosigmoid junction

Primary outcomes

1

Description

Pain intensity

Timepoint

It is before the start of the intervention and thirty minutes and one hour and three hours after the intervention.

Method of measurement

The visual scale for measuring pain intensity is a 10 cm ruler, on the left end of which the word no pain is written and on the right end the word the most severe state of pain is written. According to the amount of pain in the last 48 hours, the person puts a mark on the continuum; Then the amount of pain is measured by the researcher using the visual pain intensity measurement scale (VAS) which is standardized for pain measurement. The visual scale for measuring pain intensity from zero to ten is divided as follows: 0-1: (no pain) / 2-3: (little pain) / 4-5: (extreme pain) / 6-7: (pain) very bad)/ 8-9: (maximum pain) and 10 (unbearable pain).

2

Description

Fatigue rate

Timepoint

It is before the start of the intervention and thirty minutes and one hour and three hours after the intervention.

Method of measurement

The questionnaire (MFI) consists of 20 items and 5 subscales of general fatigue (4 questions), physical fatigue (4 questions), decreased activity (4 questions), decreased motivation (4 questions) and mental fatigue (4 questions), which It is used to measure fatigue. The scoring of the questionnaire is on a 5-option Likert scale from 1 = yes, completely true to 5 = no, completely false. Questions number 2, 5, 9, 10, 13, 14, 16, 17, 18, 19 are graded in reverse order and are graded as 5 completely correct to 1 completely incorrect. To get the overall score of the questionnaire, the scores of all items are added together. The total score of each field is 4-20 and the total score of fatigue determined by the sum of the scores of the fields can be between 20-100. A higher score indicates greater fatigue.

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: At first, the demographic information form, and visual pain level (VAS) and fatigue level (MFI) questionnaires will be completed for patients in group A. Then these people will be subjected to inhalation aromatherapy intervention with rose essence in separate rooms individually. The interventionist was present in the chemotherapy department of the mentioned hospitals, and for the participants in this group, during a session of 4:30 hours from the moment of starting the chemotherapy, 5 drops of the essential oil of the rose flower provided by Gulabgiri Kashan Company with He will pour the prepared 1.5% concentration on a piece of cotton and place it on the collar of the patient's clothes at a distance of about 20 cm from the nose. The cotton piece remains in place for 4:30 hours during chemotherapy. Again, the level of pain and fatigue of the patients will be completed based on the mentioned questionnaires in the period of thirty minutes, one hour and three hours from the start of the aromatherapy intervention for this group of patients. Then the intervention is washed out for a week so that the effects of rose water aroma therapy in this group disappear. After that, the visual pain level (VAS) and fatigue level (MFI) questionnaires will be completed again for group A patients. In the following, these people under the intervention of inhalation aroma therapy with lavender essential oil with a concentration of 1.5% prepared by Barij Essential Oil Company of Kashan will pour 5 drops of the above scent on a piece of cotton and put it on the collar of the patient's clothes with about 20 cm meters away from the nose. The cotton piece remains in place for 4:30 hours during chemotherapy. Again, the level of pain and fatigue of the patients will be completed based on the mentioned questionnaires in the period of thirty minutes, one hour and three hours from the start of the aromatherapy intervention for this group of patients.

Category

Rehabilitation

2

Description

The second intervention group: At first, the demographic information form, and visual pain level (VAS) and fatigue level (MFI) questionnaires will be completed for patients in group B. Then these people will be subjected to inhalation aromatherapy intervention with lavender essential oil in separate rooms individually. The interventionist was present in the chemotherapy department of the mentioned hospitals, and for the participants in this group, during a session of 4:30 hours from the moment of the start of chemotherapy, 5 drops of lavender scent, which was provided by Barij Essan Company of Kashan with He will pour the prepared 1.5% concentration on a piece of cotton and place it on the collar of the patient's clothes at a distance of about 20 cm from the nose. The cotton piece remains in place for 4:30 hours during chemotherapy. Again, the level of pain and fatigue of the patients will be completed based on the mentioned questionnaires in the period of thirty minutes, one hour and three hours from the start of the aromatherapy intervention for this group of patients. Then the intervention is washed out for a week so that the effects of lavender aromatherapy in this group disappear. After that, the visual pain level (VAS) and fatigue level (MFI) questionnaires will be completed

again for group B patients. In the following, these people under the intervention of inhalation aroma therapy with rose essence with a concentration of 1.5%, prepared by Gulab Giri Kashan Company, will pour 5 drops of the above scent on a piece of cotton and put it on the collar of the patient's clothes with about 20 cm meters away from the nose. The cotton piece remains in place for 4:30 hours during chemotherapy. Again, the level of pain and fatigue of the patients will be completed based on the mentioned questionnaires in the period of thirty minutes, one hour and three hours from the start of the aromatherapy intervention for this group of patients.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Semnan University of Medical Science, Kausar Hospital

Full name of responsible person
Sajad Salehipour

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Kausar educational research and treatment center, Golestan, Semnan

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Semnan

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3519899951

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+98 23 3344 1022

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2

Recruitment center

Name of recruitment center
Shahrood University of Medical Science, Bahar Hospital

Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Sajad Salehipour

Position
Faculty member

Latest degree
Master

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person
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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