

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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 Shahroud 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)

##### **Phone**

+98 23 3237 3188

##### **Email address**

ssn.shahroud@yahoo.com

##### **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 (Shahrud 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

##### Street address

Kausar educational research and treatment center, Golestan, Semnan

##### City

Semnan

##### Province

Semnan

##### Postal code

3519899951

##### Phone

+98 23 3344 1022

##### Email

kosarhos@semums.ac.ir

### 2

#### Recruitment center

##### Name of recruitment center

Shahrood University of Medical Science, Bahar Hospital

##### Full name of responsible person

Sajad Salehipour

##### Street address

Bahar educational research and treatment center, 22 Bahman St, Shahrud

##### City

Shahroud

##### Province

Semnan

##### Postal code

3614773946

##### Phone

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##### Email

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## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Semnan University of Medical Sciences

##### Full name of responsible person

Majid Mir Mohammad Khani

##### Street address

Central headquarters of Semnan University of Medical Sciences, Basij Blvd

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Semnan

##### Province

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3514799442

##### Phone

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##### Email

rds@semums.ac.ir

#### 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

##### Street address

No. 19, Alley 12, Lebanon Martyrs Street, Tehran Avenue

##### City

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##### Province

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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Sajad Salehipour

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Sajad Salehipour

**Position**

Faculty member

**Latest degree**

Master

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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