

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Comparison of aromatherapy with essential oils of Lavender and Rose on nausea and vomiting in patients undergoing chemotherapy

#### Protocol summary

##### Study aim

Determining the comparison of nausea of patients undergoing chemotherapy in the scent group of Ishtakhdos and the group of Mohammadi flowers.

##### Design

A controlled, symmetrical, single-blind, randomized, phase 3 clinical trial of 120 patients. A sealed envelope is used for randomization.

##### Settings and conduct

The study aims to reduce nausea in patients undergoing chemotherapy in Shahid Beheshti Hospital. Three drops of the relevant essential oil (2 drops of rose and 1 drop of lavender in the combined group) and distilled water in the placebo group are poured on a napkin and placed at a distance of 10-15 cm from the nose on the first night of chemotherapy by taking 5 deep breaths and He inhales from 10 pm to 6 am.

##### Participants/Inclusion and exclusion criteria

Not using aromatherapy in the last month and complementary medicine during the intervention No allergic rhinitis, asthma, chronic lung disease, and no allergy to medicinal herbs Symptoms of sensitivity to the used fragrance

##### Intervention groups

The intervention groups include: the lavender group, rose flower group, a combination of lavender and rose flower (3 drops of rose flower and 2 drops of lavender), and placebo group (distilled water). The patients in each group are asked to inhale the desired substance for three consecutive nights when they have received chemotherapy, pour it on a napkin and place it at a distance of 8 cm from the nose and inhale it from 10:00 PM to 6:00 AM.

##### Main outcome variables

Reduce nausea

#### General information

##### Reason for update

##### Acronym

LRH

##### IRCT registration information

IRCT registration number: **IRCT20220528055008N1**

Registration date: **2022-07-17, 1401/04/26**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-07-17, 1401/04/26**

Update count: **0**

##### Registration date

2022-07-17, 1401/04/26

##### Registrant information

###### Name

Zahra Kordvarkaneh

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 3274 7386

###### Email address

zahrakordvarkane955@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-10, 1401/04/19

##### Expected recruitment end date

2022-10-11, 1401/07/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of aromatherapy with essential oils of Lavender and Rose on nausea and vomiting in patients

undergoing chemotherapy

**Public title**  
The effect of lavender and rosemary essential oil on nausea and vomiting in chemotherapy patients

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Do not use aromatherapy in the past month No allergic rhinitis, asthma, chronic lung disease, sleep disorders, and other chronic diseases that affect the sense of smell No history of allergy to medicinal plants Have a course of at least 3 days of chemotherapy.  
**Exclusion criteria:**  
Occurrence of a stressful event: death of relatives, divorce, etc. during the study Using other complementary medicine interventions while studying Symptoms of sensitivity to the used fragrance Having pain while studying

**Age**  
From **18 years** old to **60 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant

**Sample size**  
Target sample size: **120**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Sampling will be available and then random allocation will be done, and every day each of the research samples that meet the criteria for entering the study will randomly select an envelope from among the sealed envelopes. In this way, the group Rosemary, Stochodos, placebo, and mixed (rosemary and Stochodos in a ratio of 3 to 2) are assigned to complete the sample size in each group and all 4 groups. The method of blinding is in the form of a blind. Only the patients did not know which group they were in. Patients receiving the scent are hospitalized in separate rooms.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Glasses of essential oils and distilled water have the same shape, size, and color.

**Placebo**  
Used

**Assignment**  
Factorial

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committee of Hamadan University of Medical Sciences

##### Street address

No. 47,Tima One Alley, Al-Ghadir Boulevard, Imam Hossein Square, Hamedan.

##### City

Hamadan

##### Province

Hamadan

##### Postal code

6513745373

##### Approval date

2022-05-06, 1401/02/16

##### Ethics committee reference number

IR.UMSHA.REC.1401.147

## Health conditions studied

### 1

#### Description of health condition studied

Nausea of chemotherapy patients

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Nausea score on visual analog scale is less than 5.

#### Timepoint

Measurement of nausea at the beginning of the intervention (before the intervention) and 1, 2, 3 and the day after inhalation of lavender, rose and placebo essential oils

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Lavender essential oil group, chemical compounds linalyl acetate 25-47, linalool 20-45, cineol maximum 2.5%, limonene maximum 1%, camphor maximum 1.2%, alpha-terpineol maximum 2%, baric essential oil company, 3 drops of essential oil Shed 10-15 cm from the nose is inhaled from 22 to 6 in the morning for 8 hours.

#### Category

**2****Description**

Rose essential oil group, 100% distilled rose essential oil compositions, and 3 drops of rose essential oil from Barich Essential Oil Company are poured on a napkin and placed at a distance of 10-15 cm from the nose from 22:00 to 6:00 in the morning and inhaled for 8 hours. Be.

**Category**

Rehabilitation

**3****Description**

Intervention group: Combined group of ostrich essential oil and rose, 2 drops of ostrich essential oil of Barich Essential Oil Company, including linalyl acetate 25-47, linalool 20-45, cineol maximum 2.5%, limonene maximum 1%, camphor maximum 1.2%, alpha-terpineol maximum 2% and 3 rose essential oils Baric Company puts 100% rose essential oil on a napkin at a distance of 10-15 cm from the nose and is inhaled from 22:00 to 6:00 in the morning.

**Category**

Rehabilitation

**4****Description**

Control group: Placebo group: 3 drops of distilled water is placed on a napkin at a distance of 10-15 cm from the nose and is inhaled from 8 pm to 6 am for 8 hours.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Beheshti hospital

**Full name of responsible person**

Zahra Kordvarkaneh

**Street address**

No. 47, Tima One Alley, Al-Ghadir Boulevard, Imam Hossein Square, Hamedan.

**City**

Hamadan

**Province**

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**Postal code**

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**Phone**

+98 81 3274 7386

**Email**

zahrakordvarkane955@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Shirin Sharifi

**Street address**

No. 47, Tima One Alley, Al-Ghadir Boulevard, Imam Hossein Square, Hamedan.

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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**

Hamedan University of Medical Sciences

**Proportion provided by this source**

80

**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**

Hamedan University of Medical Sciences

**Full name of responsible person**

Zahra Kordvarkaneh

**Position**

Nurse

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Zahra Kordvarkaneh

**Position**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Zahra Kordvarkaneh

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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

Yes - There is 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

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is 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

### Title and more details about the data/document

All potential data can be shared after unidentified individuals. Includes: study results, severity of nausea of drugs, age of people, types of cancer and nausea of related drugs

### When the data will become available and for how long

6 months after printing

### To whom data/document is available

All researchers and patients

### Under which criteria data/document could be used

It can be used if the results are generalized to the type of drug, not the type of cancer and its association with nausea.

### From where data/document is obtainable

By e-mail address

### What processes are involved for a request to access data/document

After sending an email from the applicant, the file will be provided to the person 1 month later.

### Comments