# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## The survey of the effect of aromatherapy with Rosa damascena essence on chemotherapy-induced nausea and vomiting: a randomized clinical trial

## Protocol summary

**Study aim**
Determining the effect of aromatherapy with Rosa damascena essence on chemotherapy-induced nausea and vomiting

**Design**
Phase 3 randomized clinical trial on 62 patients

**Settings and conduct**
This study will be conducted on cancer patients undergoing chemotherapy in the oncology department of Shahid Jalil Hospital in Yasuj city. In the intervention group, a cotton ball soaked in five drops of rose essential oil will be placed 30 centimeters away from the patient's nose. Patients will be instructed to breathe naturally for 20 minutes twice a day, and this process will be continued for three consecutive days

**Participants/Inclusion and exclusion criteria**
Confirmation of cancer diagnosis by an oncologist. Completion of at least one cycle of chemotherapy, despite the use of chemotherapy-induced antiemetic drugs, including cyclophosphamide, cisplatin, carboplatin, and doxorubicin, either as single-agent or multi-agent chemotherapy. No history of nausea and vomiting due to reasons other than chemotherapy. Absence of gastrointestinal issues and diarrhea. Age above 18 years. Non-pregnant and not breastfeeding. No use of sedative or antidepressant medications.

**Intervention groups**
In this study, participants will be selected through a convenient sampling method and will be randomly assigned to either the intervention or control group. In the intervention group, aromatherapy with rose essential oil will be combined with routine treatments, while the control group will receive the standard treatments (Granisetron, Dexamethasone, and Aprepitant).

**Main outcome variables**
Chemotherapy-induced nausea and vomiting

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20121208011692N4**
Registration date: **2025-02-18, 1403/11/30**
Registration timing: **prospective**

Last update: **2025-02-18, 1403/11/30**
Update count: **0**

**Registration date**
2025-02-18, 1403/11/30

**Registrant information**

**Name**
Ardeshir Afrasiabifar

**Name of organization / entity**
Yasuj University of Medical Sciences

**Country**
Iran (Islamic Republic of)

**Phone**
+98 74 2223 4115

**Email address**
afrasiabifar.ardashir@yums.ac.ir

**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2025-02-19, 1403/12/01

**Expected recruitment end date**
2025-05-21, 1404/02/31

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**

empty

**Scientific title**
The survey of the effect of aromatherapy with Rosa damascena essence on chemotherapy-induced nausea and vomiting: a randomized clinical trial

**Public title**
The survey of the effect of aromatherapy on patients undergoing chemotherapy

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Definite diagnosis of cancer by an oncologist Completed at least one course of chemotherapy with antiemetic chemotherapy drugs including cyclophosphamide, cisplatin, carboplatin and doxorubicin in a single or multiple regimen No history of nausea and vomiting for reasons other than chemotherapy No digestive problems or diarrhea Age over 18 Not pregnant or breastfeeding Not taking sedatives and antidepressants

**Exclusion criteria:**
Lack of study inclusion criteria Unwillingness to participate in the study

**Age**
From **18 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **62**

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

**Randomization description**
Participants eligible for the study will be selected using convenience sampling and will be randomly assigned to one of two intervention or control groups through block random assignment. First, we calculate the number of samples in each block by multiplying the number of study groups (two groups) by 2, resulting in a block size of 4. Next, we determine the total number of arrangements of individuals using a factorial calculation (1×2×3×4=4!=24), which indicates there will be 24 different blocks. Each block will contain 4 participants (2 from each group), arranged differently. The blocks will be randomly selected for placement, meaning that when a block is chosen, it will contain those 4 participants. The allocation method is clearly defined. The potential arrangements of participants within the blocks are as follows: ABCD, ABDC, ACBD, ACDB, ADBC, ADCB, BACD, BADC, BCAD, BCDA, BDAC, BDCA, CABD, CADB, CBAD, CBDA, CDAB, CDBA, DABC, DACB, DBAC, DBCA, DCAB, and DCBA. The group labels will be randomly assigned and drawn, with A representing the intervention group, while B and C designate the control group, and D also represents the intervention group. Each participant will be given a code, which corresponds with the block random allocation list, enabling them to be assigned to either the intervention or control group.

**Blinding (investigator's opinion)**
Not blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**
Participants eligible for the study will be selected through convenience sampling and will be randomly assigned to one of the two intervention and control groups through block random assignment. The total number of samples is 62, with 31 in each group.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics committee of Yasuj University of Medical Sciences

**Street address**
Yasuj University of Medical Sciences

**City**
Yasuj

**Province**
Kohgilouyeh-va-Boyrahmad

**Postal code**
7591615486

**Approval date**
2025-01-29, 1403/11/10

**Ethics committee reference number**
IR.YUMS.REC.1403.121

## Health conditions studied

### 1

**Description of health condition studied**
Cancer

**ICD-10 code**
R97.1

**ICD-10 code description**
Elevated cancer antigen 125 [CA 125]

## Primary outcomes

### 1

**Description**
Chemotherapy-induced nausea and vomiting score on the MAT questionnaire

**Timepoint**
In 3 cycles of chemotherapy, 2 times per cycle (in the first 24 hours and after the first 24 hours after chemotherapy)

**Method of measurement**
Multinational Association of Supportive Care in Cancer Antiemesis Tool

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
Intervention group: In the intervention group, aromatherapy with Rosa damascena essence will be performed alongside routine treatments. The intervention will be carried out from the day of chemotherapy until the third day after chemotherapy and will continue for 3 consecutive cycles. To ensure that the participants are not allergic to the essential oil, a skin test will be performed on all patients in the intervention group. In this test, a drop of Rosa damascena essence with a concentration of 40% will be placed on the back of the patient's hand. After two minutes of contact with the skin, the back of the patient's hand will be examined for any allergic reaction (such as redness, hives, itching, etc.). Only those who do not have any allergy symptoms will be included in the study. In the next step, a cotton ball soaked in five drops of Rosa damascena essence will be placed 30 centimeters from the patient's nose. Patients are advised to breathe normally twice a day, for 20 minutes each time, and continue this process for three consecutive days.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Shahid Jalil Hospital, Yasuj
**Full name of responsible person**
Afrasiabirar Ardashir
**Street address**
Yasuj University of Medical Sciences
**City**
Yasuj
**Province**
Kohgilouyeh-va-Boyrahmad
**Postal code**
7591615486
**Phone**
+98 917 341 1267
**Email**
afrasiabifar.ardashir@yums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Yasouj University of Medical Sciences
**Full name of responsible person**
Seyed Amin Hosseini Motlagh
**Street address**
Motahari Blvd, Research and Technology Department, Yasuj University of Medical Sciences
**City**
Yasuj
**Province**
Kohgilouyeh-va-Boyrahmad
**Postal code**
7591741417
**Phone**
+98 74 3334 6078
**Email**
aminhomo@yahoo.com
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Yasouj 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**
Yasouj University of Medical Sciences
**Full name of responsible person**
Afrasiabifar Ardashir
**Position**
Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nursery
**Street address**
Yasuj University of Medical Sciences
**City**
Yasuj
**Province**
Kohgilouyeh-va-Boyrahmad
**Postal code**
7591615486
**Phone**
+98 74 3323 4115
**Email**

afrasiabifar.ardashir@yums.ac.ir

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Yasouj University of Medical Sciences
**Full name of responsible person**
Afrasiabifar Ardashir
**Position**
professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nursery
**Street address**
Yasuj University of Medical Sciences
**City**
Yasuj
**Province**
Kohgilouyeh-va-Boyrahmad
**Postal code**
7591615486
**Phone**
+98 74 3323 4115
**Email**
afrasiabifar.ardashir@yums.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Yasouj University of Medical Sciences
**Full name of responsible person**
Afrasiabifar Ardashir
**Position**
professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Nursery
**Street address**
Yasuj University of Medical Sciences
**City**
Yasuj
**Province**
Kohgilouyeh-va-Boyrahmad
**Postal code**
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**Phone**
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**Email**
afrasiabifar.ardashir@yums.ac.ir

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available
**Study Protocol**
Yes - There is a plan to make this available
**Statistical Analysis Plan**
Yes - There is 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**
Yes - There is a plan to make this available
**Data Dictionary**
Yes - There is a plan to make this available
**Title and more details about the data/document**
Data can be shared after de-identifying individuals.
**When the data will become available and for how long**
Access period starts 6 months after results are published.
**To whom data/document is available**
For scientific researchers
**Under which criteria data/document could be used**
...
**From where data/document is obtainable**
09173411267 afrasiabifar.ardashir@yums.ac.ir
**What processes are involved for a request to access data/document**
By email and phone call
**Comments**