

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation effect of aromatherapy with rose essential on nausea and vomiting in patients undergoing chemotherapy: A randomized control trial

Protocol summary

Study aim

Determining the effect of aromatherapy with rose essential on the severity of nausea and vomiting in patients undergoing chemotherapy.

Design

Clinical trial with control group, with parallel group, no blinding, Randomized, phase 3 on 66 patients, for randomization, Sealed Envelope Ltd's online randomization service will be used

Settings and conduct

This research will be carried out in Rasht's Beesat Clinic in the chemotherapy unit. The severity of nausea and vomiting is evaluated once three hours before chemotherapy, after that 5 minutes before the start of chemotherapy, 3 drops of rose essential with a concentration of 40% were poured on sterile gauze 5x5. It is connected to the patient's collar with a safety pin. This intervention is performed before each cycle of chemotherapy. Then the severity of nausea and vomiting is evaluated in three six-hour intervals. But in the control group, no intervention is used as a placebo because of the smell of roses.

Participants/Inclusion and exclusion criteria

Inclusion criteria : age over 18 years, ability to understand and speak persian, having the experience of at least one cycle of chemotherapy and prescribing chemotherapy drugs that are classified as severe in terms of nausea and vomiting. Non-entry criteria: allergy to herbal medicines and essential oils, suffering from brain malignancies and other metastases, presence of hepatitis and lack of sense of smell.

Intervention groups

In this study, the intervention group receives aromatherapy, routine care and routine nausea and vomiting medications. The severity of nausea and vomiting is evaluated before and after chemotherapy. The control group is a group that receives routine care

and medication, but does not receive aromatherapy.

Main outcome variables

Nausea and vomiting severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100921004787N7**

Registration date: **2022-08-31, 1401/06/09**

Registration timing: **prospective**

Last update: **2022-08-31, 1401/06/09**

Update count: **0**

Registration date

2022-08-31, 1401/06/09

Registrant information

Name

Tahereh Khaleghdoost Mohammadi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1555 5058

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation effect of aromatherapy with rose essential on nausea and vomiting in patients undergoing chemotherapy: A randomized control trial

Public title
Effect rose essential on nausea and vomiting of chemotherapy

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Age over 18 years Having the experience of at least one cycle of chemotherapy The ability to understand and speak Persian Prescribing chemotherapy drugs that are classified as severe in terms of nausea and vomiting.
Exclusion criteria:
 The presence of hepatitis Suffering from brain malignancies and other metastases Allergy to herbal medicines and essential oils Lack of sense of smell

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
All eligible patients will be divided using the block randomization method with the size of 4 and 6 blocks equally (ratio 1:1) into aromatherapy groups with rose essence and control. Sealed Envelope Ltd.'s online randomization service will be used to generate the randomization list. Also used for concealment are sequentially numbered opaque sealed envelopes(SNOSE).

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical sciences

Street address

Student of Nursing and Midwifery faculty, Shahid Beheshti Highway, Rasht

City

Rasht

Province

Guilan

Postal code

4146939841

Approval date

2022-07-13, 1401/04/22

Ethics committee reference number

IR.GUMS.REC.1401.220

Health conditions studied

1

Description of health condition studied

Nausea and vomiting severity after chemotherapy

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Nausea and vomiting severity

Timepoint

Measuring the severity of nausea and vomiting once three hours before the intervention and then in three six-hour intervals after the intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group in which severity of nausea and vomiting are evaluated once in three hours before chemotherapy. Then, in the patient's room, five minutes before the start of chemotherapy, 3 drops of rose essential with a concentration of 40%, which is from an Iranian plant company(Lavender), is poured on sterile gauze 5*5, then the gauze is adjusted so that it is

connected to the patient's collar by a pin at the closest distance (twenty centimeters) to the patient's nose. then the patient is asked to breathe normally for three minutes, and this is done every time before each cycle of chemotherapy. After the end of the chemotherapy session, the severity of nausea and vomiting of the client will be evaluated during three six-hour intervals using the Visual Analogue Scale tool. These patients will follow all the doctor's prescriptions and usual care such as taking anti-nausea drugs, corticosteroids, benzodiazepines and other drugs.

Category

Prevention

2

Description

Control group: A group in which no intervention is used as a placebo because of the smell of roses. So the severity of nausea and vomiting will be assessed once in a three-hour period before chemotherapy. Also, after the end of the chemotherapy session, the severity of nausea and vomiting of the patients will be examined during three six-hour intervals using the Visual Analogue Scale tool. These patients will follow all the doctor's prescriptions and usual care such as taking anti-nausea drugs, corticosteroids, benzodiazepines and other drugs.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Subspecialty Clinic Beesat

Full name of responsible person

Pouria Takasi

Street address

Subspecialty Clinic Beesat, Enghelab Street, Rasht

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4136617865

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Mohamad Reza Naghipoor

Street address

Namjoo Street Rasht

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4144666949

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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

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Pouria Takasi

Position

Master Science Student of Medical Surgical Nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Rasht University of Medical Sciences
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Position
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Person responsible for updating data

Contact

Name of organization / entity
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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All original data can be shared after de-identifying individuals.

When the data will become available and for how long

Beginning of access from 2023

To whom data/document is available

Researchers of universities of medical sciences

Under which criteria data/document could be used

Raw data is not made available to everyone. If using published results, reference should be made to the article. The requesting researcher is allowed to carry out this method in similar studies.

From where data/document is obtainable

Pouria Takasi; email: pooryapin380@gmail.com Tahereh Khaleghdoost Mohammadi; email: khaleghdoost@gums.ac.ir

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

First, send your request via email. If approved, the requested information will be sent in one working week.

Comments