Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Cardamom aromatherapy on nausea and vomiting induced by chemotherapy in cancerous patients

Protocol summary

Summary

The aim of this study is to determine the effects of Cardamom aromatherapy on the nausea and vomiting induced by chemotherapy in cancerous patients. The design is a categorized-blocked randomized clinical trial conducted through the single-blinded randomized with a placebo control group. The categorized-blocked allocation method will be based on the type of chemotherapy medication and gender. 58 cancer patients undergoing chemotherapy in the Shaheed Beheshti Hospital and of Imam Khomeini Clinic in Hamadan will be participated. Inclusion criteria are: having aged 65-18 years and nausea in the acute phase of chemotherapy no history of asthma and vegetable essence oils allergies. Exclusion criteria include: having vomiting without nausea before performing the intervention. The patients will be randomly assigned to the experimental group or the control group after expressing their nausea and signing the informed consent. The patients' nausea is determined by VAS at the entrance to the study. Then, the patients in the experimental group will receive three deep breaths with the essential oil of cardamom soaked pads and the patients in the control group will receive three deep breaths with the placebo (distilled water) soaked pads. 5 minutes later, the nausea of the patients in the both groups are measured by VAS. If nausea remains, the intervention will be repeated and again after 5 minutes the nausea is measured according to VAS. The frequency of their retching and vomiting in the acute phase of chemotherapy are assessed after the implementation of research protocols in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071013936N1**

Registration date: **2013-12-06, 1392/09/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-06, 1392/09/15

Registrant information

Name

Zahra Khalili

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1828 0332

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Hamadan University of Medical Sciences

Expected recruitment start date

2013-12-06, 1392/09/15

Expected recruitment end date

2014-05-05, 1393/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Cardamom aromatherapy on nausea and vomiting induced by chemotherapy in cancerous patients

Public title

The effects of the Cardamom aroma on the nausea and vomiting induced by chemotherapy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: age between 18-65 years old; having a healthy olfactory; no history of asthma; no allergies to herbal essences; no history of chronic obstructive pulmonary disease; absence nausea due to the other reason verified by the physician; expression nausea after starting chemotherapy in the acute phase. Exclusion criterion: vomiting without nausea before the intervention protocol.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of the Hamadan University of Medical Sciences

Street address
Fahmideh St., University of Medical Sciences, Hamedan

City
Hamaden

Postal code
8698365178

Approval date
2013-09-09, 1392/06/18

Ethics committee reference number
1683/9/35/16/پ

Health conditions studied

1

Description of health condition studied
Malignant neoplasm

ICD-10 code
C00-97

ICD-10 code description
Malignant neoplasms

Primary outcomes

1

Description
The severity of nausea induced by chemotherapy

Timepoint
Before the experiment, 5 minutes after the first intervention, and 5 minutes after second intervention

Method of measurement
Visual Analog Scale (VAS)

Secondary outcomes

1

Description
Number of vomiting

Timepoint
In the acute phase after research protocol intervention

Method of measurement
Frequency and/or multiple-choice questionnaire

2

Description
Number of retching

Timepoint
In the acute phase of chemotherapy after protocol implementation

Method of measurement
Frequency and/or multiple-choice questionnaire

Intervention groups

1

Description
The patients in the control group will receive the placebo. In order to prepare the placebo, two 2" × 2" gas pads will be soaked with 2 ml of distilled water put in a zipper plastic bag. The patients asked to inhale three deep breaths of placebo after rating her/him nausea severity according to VAS. 5 minutes later, the nausea of the patients is measured by VAS. Then, if nausea remains, the intervention will be repeated and again after 5 minutes the nausea is measured according to VAS. The frequencies of their retching and vomiting in the acute phase of chemotherapy are assessed after the implementation of research protocol.

Category
Placebo

2

Description
The patients in the experimental group will receive the essential oil of cardamom. In order to prepare the essential oil of cardamom, two 2" × 2" gas pads will be soaked with 2 drops of essential oil of cardamom and 2 ml of distilled water put in a zipper plastic bag. The patients asked to inhale three deep breaths of the cardamom essential oil pads after rating her/him nausea severity according to VAS. 5 minutes later, the nausea of the patients is measured by VAS. Then, if nausea remains, the intervention will be repeated and again after 5 minutes the nausea is measured according to VAS. The frequencies of their retching and vomiting in the acute phase of chemotherapy are assessed after the implementation of research protocol.

Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Educational and Medical Center
Full name of responsible person
Zahra Khalili
Street address
Hamedan, Eram Blv. Beheshti Educational and Medical Center
City
Hamadan

2

Recruitment center
Name of recruitment center
Clinic of Imam Khomeini
Full name of responsible person
Zahra Khalili
Street address
Hamadan, Mirzadeheshghi St. Clinic of Imam Khomeini
City
Hamadan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamadan University of Medical Sciences, Vice chancellor for Research.
Full name of responsible person
Dr. Saeed Bashirian
Street address
Fahmideh St., University of Medical Sciences, Hamadan
City
Hamadan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamadan University of Medical Sciences, Vice chancellor for Research.
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Hamadan, University of Medical Sciences
Full name of responsible person
Zahra Khalili
Position
Critical Care Nursing Graduate Student
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Mother and Child Care Research Center, Hamedan University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty