The effect of aromatherapy with lemon essential oils on nausea, vomiting and anxiety in patients undergoing chemotherapy

Protocol summary

**Study aim**
Determining the effect of sour lemon scent on vomiting nausea and anxiety of patients undergoing chemotherapy

**Design**
In this randomized clinical trial, patients will be randomly assigned to two groups of 25 people.

**Settings and conduct**
Aromatherapy during chemotherapy will be performed for 4 weeks in the chemotherapy department of Shahid Beheshti Hospital in Kashan.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria:
- Age over 18 years
- Patients with breast and esophageal, gastric and intestinal cancers
- Healthy sense of smell
- No history of asthma or chronic obstructive pulmonary disease
- Lack of sensitivity to plant essential oils
- Have a nausea score of at least 2
- Do not take sedatives or other medications to reduce anxiety for six weeks before the procedure
- Not addicted to drugs
- Chemotherapy once a week
- Patients with stage I, II cancer

Exclusion criteria:
- Vomiting due to other diseases diagnosed by an oncologist
- The patient's inability to determine the severity of nausea despite the instructions
- Use complementary medicine methods to relieve anxiety or nausea and vomiting

**Intervention groups**
In the intervention group, its lemon scent will be used for 4 weeks during chemotherapy. In the control group, placebo will be used for 4 weeks.

**Main outcome variables**
Nausea and vomiting and anxiety

**General information**

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: IRCT20111210008348N45

**Registration date:** 2020-07-06, 1399/04/16
**Registration timing:** registered_while_recruiting

**Last update:** 2020-07-06, 1399/04/16
**Update count:** 0

**Registrant information**
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**Recruitment status** Recruitment complete

**Funding source**

**Expected recruitment start date** 2020-06-06, 1399/03/17
**Expected recruitment end date** 2020-09-20, 1399/06/30
**Actual recruitment start date** empty
**Actual recruitment end date** empty
**Trial completion date** empty

**Scientific title**
The effect of aromatherapy with lemon essential oils on nausea, vomiting and anxiety in patients undergoing chemotherapy

**Public title**
The effect of aromatherapy with lemon essential oils on nausea, vomiting and anxiety in patients undergoing chemotherapy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients over 18 years Patients with breast and esophageal, gastric and intestinal cancers (due to the same drugs used) Healthy sense of smell: Measurement by smelling alcohol No history of asthma or chronic obstructive pulmonary disease Lack of sensitivity to plant essential oils Having a minimum nausea score of 2 based on vas criteria on the first day of study No more anxiety score of 63 Do not take sedatives or other medications (such as using herbal essential oils, regular exercise) to reduce anxiety for six weeks before the intervention Not addicted to drugs Perform chemotherapy once a week Patients with stage I, II cancer The goal of chemotherapy is therapy

Exclusion criteria:
Use of other Complementary therapies

Age
From 18 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 50

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation in two groups of intervention and control will be simple randomization. Randomization is carried out by creating a random sequence of numbers using on an line randomizer tool (https://www.randomizer.org).

Blinding (investigator's opinion)
Not 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 Kashan University of Medical Sciences

Street address
Ravand Street, Kashan University of Medical Sciences.

City
Kashan

Province
Isfihan

Postal code
8715981151

Approval date
2020-06-06, 1399/03/17

Ethics committee reference number
IR.KAUMS.NUHEPM.REC.1399.019

Health conditions studied

1

Description of health condition studied
Nausea and vomiting

ICD-10 code
R11

ICD-10 code description
Nausea and vomiting

2

Description of health condition studied
Anxiety

ICD-10 code
F06.4

ICD-10 code description
Anxiety disorder due to known physiological condition

Primary outcomes

1

Description
Nausea, vomiting

Timepoint
Before and during the intervention

Method of measurement
Visual criteria for nausea and vomiting

Secondary outcomes

1

Description
Anxiety

Timepoint
Before and during the study

Method of measurement
Spielberger's Anxiety Questionnaire

Intervention groups

1

Description
In addition to the usual care of the ward (Geranisetron and Dexamethasone), the researcher pours a drop of
sour lemon essential oil onto a paper towel with a drip during chemotherapy and attaches it to the collar of the research unit with a pin, then asks him to breathe normally. This method will be used once a week (during chemotherapy) for 4 weeks. The intervention of 5 minutes before the start of chemotherapy until receiving chemotherapy treatment for patients will be done. Aromatherapy with lemon essential oil is performed when the patient is lying on the bed and the paravan is lying around his bed.

Category
Treatment - Other

2

Description
Control group: In addition to the usual care of the ward (Geranisetron and Dexamethasone), the researchist pours 3 ml of water (placebo) poured on the paper and the collar is connected sick during chemotherapy. This method will be used once a week (during chemotherapy) for 4 weeks. The intervention of 5 minutes before the start of chemotherapy until receiving chemotherapy treatment for patients will be done. Aromatherapy with lemon essential oil is performed when the patient is lying on the bed and the paravan is lying around his bed.

Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Chemotherapy, Shahid Beheshti Hospital, Kashan

Full name of responsible person
Morteza Moghari

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3 Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Kashan 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
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Position
Student

Latest degree
Bachelor

Other areas of specialty/work
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Sharing plan
Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Data of participants are confidential
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable