Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effects of Inhalation of Rosa Damascene Essential Oil on Fatigue and Anxiety among Cancer Patients Receiving Chemotherapy

Protocol summary

Study aim

Determining the Effect of Inhalation Therapy on Essential Oil of Damask Rosea on the Fatigue and Anxiety of Cancer Patients Under Chemotherapy

Design

This clinical trial was conducted with a control group at Khansaria Hospital in Arak. 64 cancer patients undergoing chemotherapy were selected based on the inclusion criteria by simple random sampling and the random number block using letters A and B to 2 groups: Inhaled aromatherapy (32 patients) and control group (32) .

Settings and conduct

Khansari Hospital in Arak.

Participants/Inclusion and exclusion criteria

Patients with head and neck cancer

Intervention groups

The fatigue and anxiety levels of the patients were assessed by a researcher before intervention using the BFI and Spielberger questionnaires. by the assistant Using a pipette, distilled water was dropped on a 10 × 10 cm gauze which was attached to the collar of the patient's shirt, about 20 cm from their nose.The patients in the intervention group in addition to the usual nursing care, inhaled 5 drops of damask rose essential oil 40% Prepared by the pharmacist, for 20 min, for 3 day consecutive , while In the control group, addition to the usual nursing care, the patients inhaled five drops of distilled water as placebo through the same procedure. researcher measured Patients' anxiety 20 minutes after intervention by using the Spielberger's questionnaire .researcher measured Patients' fatigue in 30 and 60 minutes after intervention by using the BFI questionnaire.

Main outcome variables

fatigue and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111015007803N3**
Registration date: **2018-08-29, 1397/06/07**
Registration timing: **retrospective**

Last update: **2018-08-29, 1397/06/07**
Update count: **0**

Registration date

2018-08-29, 1397/06/07

Registrant information

Name

Faraz Mojab

Name of organization / entity

Shahid Beheshty University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 0061

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-20, 1397/01/31

Expected recruitment end date

2018-06-21, 1397/03/31

Actual recruitment start date

2018-06-18, 1397/03/28

Actual recruitment end date

2018-08-19, 1397/05/28

Trial completion date

empty

Scientific title
The Effects of Inhalation of Rosa Damascene Essential Oil on Fatigue and Anxiety among Cancer Patients Receiving Chemotherapy

Public title
The Effects of Inhalation of Rosa Damascene Essential Oil on Fatigue and Anxiety among Cancer Patients Receiving Chemotherapy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age greater than 18 and less than 70 years Cancer patients with at least one chemotherapy course with a 21 day interval from the last session. Detect stage 2, 3, and 4 of all cancers other than head and neck and lung with the opinion of the relevant physician. Full vigilance No history of cigarette and drug addiction Earning a score higher than 20 after responding to the Spielberger questionnaire in the pre-test Non-use of benzodiazepines, tranquillizers and opioids during intervention Without a history of migraine and chronic headaches Non-impaired sense of smell (without obstruction and nasal congestion) and healthy sense of smell) through smelling of alcohol). Inability of the patient to answer questions (in terms of physical and mental status) lack of patient psychiatric problems (hospitalization or other medical treatment is not due to mental disorders). Stable and stable hemodynamic status Not having a history of allergy to the smell of herbs and any scent or fragrance Not having respiratory diseases The desire to participate in research Do not use any other scent during the study

Exclusion criteria:
Patients with head and neck cancer

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **64**
Actual sample size reached: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
The method of sampling in this study was simple random sampling. How to place the selected samples in the test and control group based on the random number block method. From the first patient, one of the letters A and B was randomly selected. The first patient in the experimental group and the second patient in the control group were placed and then the patients were placed in the test and control groups, respectively. 32 patients in the experimental group and 32 patients in the control group were considered.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a double-blind clinical trial in which patients, who measure the outcomes of the study (the researcher), are unaware of how the patients received the intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics Committee of Islamic Azad University, Tehran Medical Branch

Street address
Shariati St., Khaghani St. - Islamic Azad University, Tehran Medical Sciences

City
Tehran

Province
Tehran

Postal code
1916893813

Approval date
2017-07-26, 1396/05/04

Ethics committee reference number
IR.IAU.TMU.REC.1396.68

Health conditions studied

1

Description of health condition studied
People with cancer under chemotherapy

ICD-10 code
C80.9

ICD-10 code description
Malignant neoplasm, unspecified

Primary outcomes

1

Description
Fatigue of patients with cancer under chemotherapy

Timepoint
Before the intervention and 30, 60 minutes after the intervention for three consecutive days

Method of measurement
Standard Fatigue Fatigue Questionnaire (BFI)

2

Description
Anxiety in patients with cancer under chemotherapy
Timepoint
Before the intervention and 20 minutes after the intervention for three consecutive days
Method of measurement
Spilberger Situational Anxiety Inventory

Secondary outcomes

empty

Intervention groups

1

Description
The fatigue and anxiety levels of the patients were assessed by a researcher before intervention using the BFI and Spielberger questionnaires. by the assistant Using a pipette, distilled water was dropped on a 10 × 10 cm gauze which was attached to the collar of the patient's shirt, about 20 cm from their nose.The patients in the intervention group in addition to the usual nursing care, inhaled 5 drops of damask rose essential oil 40% Prepared by the pharmacist, for 20 min, for 3 day consecutive , while In the control group, addition to the usual nursing care, the patients inhaled five drops of distilled water as placebo through the same procedure. researcher measured Patients' anxiety 20 minutes after intervention by using the Spielberger's questionnaire .researcher measured Patients' fatigue in 30 and 60 minutes after intervention by using the BFI questionnaire.
Category
Treatment - Other

2

Description
Control group: The fatigue and anxiety levels of the patients were assessed by a researcher before of intervention using the BFI and Spielberger questionnaires. by the assistant Using a pipette, distilled water was dropped on a 10 × 10 cm gauze which was attached to the collar of the patient's shirt, about 20 cm from their nose. In the control group, addition to the usual nursing care, the patients inhaled five drops of distilled water as placebo through the same procedure. researcher measured Patients' anxiety 20 minutes after intervention by using the Spielberger's questionnaire .researcher measured Patients' fatigue in 30 and 60 minutes after intervention by using the BFI questionnaire.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Arak Khansari Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
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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
Islamic Azad University
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
Arak University of Medical Sciences
Full name of responsible person
Elham Khosrobeigi
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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
The total potential data can be shared after unidentifiable people
When the data will become available and for how long
Starting the access period from 1397
To whom data/document is available
Elham Khosrobeigi
Under which criteria data/document could be used
The total potential data after unidentifiable people is for sharing analysis
From where data/document is obtainable
elhamkhosrobeigi65@yahoo.com
What processes are involved for a request to access data/document
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