

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of aromatherapy on anxiety, nausea and vomiting of patients undergoing abdominal surgery

Protocol summary

Study aim

The effect of aromatherapy on nausea, vomiting and anxiety

Design

All patients undergoing abdominal surgery are enrolled in this study. Then, patients with inclusion criteria were randomly assigned to two groups of control and intervention using a computer generated random number table. Each group is assigned a code to hide the groups.

Settings and conduct

Valiasr and Amir Al-Momenin hospital, double blind

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Age 18 years old 2. Have a healthy sense of smell 3.No history of smoking 4. Not a history of allergy and allergy to medicinal herbs 5. No history of asthma or respiratory diseases 6. Alertness and ability to speaking 7. Reading and writing literacy, ability to understand Persian language 8. No history of new crisis over the past six months 9. Do not history of previous surgery Non-compliance criteria: 1. Use of other complementary and alternative methods during the study 2. Use hypnotic and antipyretic drugs, antidepressants and anti-anxiety during the study 3. Use of drugs that affect nausea and vomiting before starting the study

Intervention groups

In the intervention group aromatherapy with lime oil is performed in the department (3 times). In the control group, aromatherapy with water (as placebo) is performed (three times).

Main outcome variables

Nausea, vomiting, anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180103038211N9**

Registration date: **2019-08-01, 1398/05/10**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-01, 1398/05/10**

Update count: **0**

Registration date

2019-08-01, 1398/05/10

Registrant information

Name

Fahime Davodabady

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3226 7610

Email address

F_davodabady@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-11-21, 1398/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aromatherapy on anxiety, nausea and vomiting of patients undergoing abdominal surgery

Public title

Investigating the effect of aromatherapy in abdominal

surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Abdominal Surgery Have a healthy sense of smell

Exclusion criteria:

History of smoking History of allergy and allergy to medicinal herbs A history of asthma or respiratory illness The history of a new crisis, such as the death of a first-degree relative, the divorce of a person or parent during the past six months History of previous surgery

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients undergoing abdominal surgery are enrolled in the study. Then, a number is given to qualified patients, respectively, entering the study from 1 to n. Participants are randomly assigned to two groups of intervention and control by using a computer generated random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants are divided into two groups of intervention and control. One of the groups is A and the other is called B. Before and after the intervention, the information is collected by the evaluator of the outcome that is unaware of the grouping of the groups. Data analysis is also done by someone who is unaware of the allocation of groups. Participants in the study received similar interventions and were unaware of the division of the groups and the type of substance used in the aromatherapy and the presence of the control group. Containers are a form and a color.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Basij Square, Sardasht

City

Arak

Province

Markazi

Postal code

6941-7-38481

Approval date

2019-05-26, 1398/03/05

Ethics committee reference number

IR.ARAKMU.REC.1398.071

Health conditions studied

1

Description of health condition studied

Multiple sclerosis

ICD-10 code

G35

ICD-10 code description

Demyelinating diseases of the central nervous system

Primary outcomes

1

Description

Level of anxiety

Timepoint

Measure one hour before surgery, 20 minutes before surgery, one hour and two hours after full vigilance after surgery

Method of measurement

Anxiety Visual Analog Scale

2

Description

Nausea

Timepoint

one hour and two hours after full vigilance after surgery

Method of measurement

Visual Analog Scale Nausea

3

Description

Vomiting

Timepoint

one hour and two hours after full vigilance after surgery

Method of measurement

Measures based on occurrence or non-occurrence

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: One hour before surgery, after surgery, entering to the department, one hour after arrival to the department (three times), aromatherapy is done; for aromatherapy, 2-3 drops of lime oil on a cotton ball Shed and is placed 15 to 20 cm from the patient's nose for 5 to 10 minutes.

Category

Treatment - Other

2

Description

Control group: Aromatherapy with water (as placebo) is performed three times.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr and Amir Al-Momenin Hospital

Full name of responsible person

Fahimeh Davodabady

Street address

Arak University of Medical Sciences, Basij Square, Sardasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjomandzadegan

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arjomandzadegan@arakmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Fahimeh Davodabady

Position

Instructor

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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