# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 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

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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