# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 2026

## Investigating the effect of Lemon scent on patients before rhinoplasty surgery

## Protocol summary

**Study aim**

Determination and comparison of the average anxiety score of rhinoplasty candidate patients, before and after the intervention in the intervention group Determining and comparing the average anxiety score of rhinoplasty candidate patients, before and after the intervention in the control group Determining and comparing the difference in the average anxiety score before and after the intervention in two intervention and control groups

**Design**

A controlled clinical trial, double-blind, randomized, on 30 patients, randomization using card number 1 and 2

**Settings and conduct**

At first, 30 candidates for rhinoplasty in Kashani hospital in Isfahan city, who are undergoing surgery, are selected for easy access. For the random allocation of samples, the researcher will put cards numbered 1 and 2 in an envelope according to the number of subjects, and the patients will be asked to pull a card out of the envelope. Card number 1 is placed in the test group and card number 2 is placed in the control group. In the control group, a liquid of the same color as the essence of the intervention group is used

**Participants/Inclusion and exclusion criteria**

Healthy sense of smell No history of respiratory disease Insensitivity to herbal essential oils Not taking sedatives

**Intervention groups**

After it is determined in which group the patient is placed, the intervention is carried out in such a way that, in the intervention group, he inhales 3 drops of Lemon essential oil for 20-30 minutes normally. For the control group, 3 drops of odorless liquid of the same color (water + color of the desired essential oil) is inhaled for 20-30 minutes.

**Main outcome variables**

Overt anxiety score Latent anxiety score

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20221101056375N1**
Registration date: **2022-11-14, 1401/08/23**
Registration timing: **prospective**

Last update: **2022-11-14, 1401/08/23**
Update count: **0**

**Registration date**

2022-11-14, 1401/08/23

**Registrant information**

**Name**
maryam amirshekari

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 34 4331 6688

**Email address**
amirshekarimaryam@gmail.com

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2022-11-16, 1401/08/25

**Expected recruitment end date**

2022-12-11, 1401/09/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigating the effect of Lemon scent on patients before rhinoplasty surgery

**Public title**
The effect of Lemon scent on the anxiety of patients before rhinoplasty surgery
**Purpose**
Prevention
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Healthy sense of smell No history of asthma or chronic obstructive pulmonary disease Insensitivity to herbal essential oils Not taking sedatives Not having mental and anxiety diseases
**Exclusion criteria:**
Taking sedatives Lack of consent to participate in the study History of respiratory disease History of allergy to lemon essential oil
**Age**
From **18 years** old to **50 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Participant

**Sample size**
Target sample size: **30**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
In this randomized controlled clinical trial study, at first, 30 patients who are candidates for rhinoplasty who are about to be operated on are selected in the form of easy access. The number of subjects will put cards with numbers 1 and 2 in an envelope. And the patients are asked to draw a card from the envelope. Patients with card number 1 will be in the test group and patients with card number 2 will be in the control group.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
In the intervention group, 3 drops of Lemon essential oil were dripped on the medical gauze using a dropper and attached to the patient's neck, and it is recommended to inhale normally for 20-30 minutes. For the control group, 3 drops of odorless liquid of the same color (water + color of desired essential oil) of Lemon essential oil used for the intervention group, are poured on a medical gauze and connected to the patient's collar like the intervention group, and it is recommended for 20 Inhale normally for 30 minutes.
**Placebo**
Used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Faculty of Nursing, Management and Rehabilitation - Isfahan University of Medica
**Street address**
Hazar Jarib St., Isfahan University of Medical Sciences and Health Services
**City**
Esfahan
**Province**
Isfehan
**Postal code**
81746-73461
**Approval date**
2022-10-30, 1401/08/08
**Ethics committee reference number**
IR.MUI.NUREMA.REC.1401.091

## Health conditions studied

### 1

**Description of health condition studied**
It is not a disease
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
anxiety
**Timepoint**
Before the intervention and after the intervention
**Method of measurement**
Spiegelberger questionnaire

### 2

**Description**
The percentage of people whose manifest anxiety questionnaire score is less than 40
**Timepoint**
Before and after the intervention
**Method of measurement**
Calculation of the score of the Spiegelberger questionnaire

### 3

**Description**
The percentage of people whose overt anxiety questionnaire score is above 60
**Timepoint**
Before and after the intervention
**Method of measurement**
Calculation of the score of the Spiegelberger

questionnaire

**4**

**Description**
The percentage of people whose anxiety questionnaire score is above 60
**Timepoint**
Before and after the intervention
**Method of measurement**
Calculation of the score of the Spiegelberger questionnaire

**5**

**Description**
The percentage of people whose hidden anxiety questionnaire score is less than 40
**Timepoint**
Before and after the intervention
**Method of measurement**
Calculation of the score of the Spiegelberger questionnaire

## Secondary outcomes

**1**

**Description**
Overt anxiety score
**Timepoint**
Before and after the intervention
**Method of measurement**
Spiegelberger questionnaire

**2**

**Description**
Latent anxiety score
**Timepoint**
Before and after the intervention
**Method of measurement**
Spiegelberger questionnaire

## Intervention groups

**1**

**Description**
Intervention group: 3 drops of Lemon essential oil from Kashan Barij Essential Oil Company. The main components of Lemon essential oil used include: limonene (68.2%), betapinene (12.8%), gamma terpinene (8.8%) and alpha pinene (2.2%).Using a medical gas dropper 10x10 from Harir Novin Sepahan company, it drips and is connected to the patient's neck and it is recommended to inhale normally for 20-30 minutes.
**Category**
Prevention

**2**

**Description**
Control group: For the control group, 3 drops of odorless liquid of the same color (water + the color of the desired essential oil) of the Lemon essential oil used for the intervention group were poured on a 10 x 10 medical gauze and connected to the patient's collar as in the intervention group, and it is recommended to Inhale normally for 20 to 30 minutes.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Kashani hospital
**Full name of responsible person**
Maryam Amirshekari
**Street address**
plate 3., 5 Pasdaran Alley, second side on the left, Pasdaran St.
**City**
Jiroft
**Province**
Kerman
**Postal code**
78616-15517
**Phone**
+98 922 329 4125
**Email**
amirshekarimaryam@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Dr. Gholam Reza Askari
**Street address**
Hazar Jarib Street, Isfahan University of Medical Sciences
**City**
Esfahan
**Province**
Isfehan
**Postal code**
34567789-123
**Phone**
+98 31 3668 8138
**Fax**
+98 31 3792 8110
**Email**
askari@mui.ac.ir
**Web page address**
https://med.mui.ac.ir/fa/ejtemaei

**Grant name**
Isfahan Medical Sciences
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Esfahan University of Medical Sciences
**Proportion provided by this source**
70
**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**
Esfahan University of Medical Sciences
**Full name of responsible person**
Maryam Amirshekari
**Position**
University student
**Latest degree**
Bachelor
**Other areas of specialty/work**
surgery room
**Street address**
Pasdaran Alley 5,Pasdaran Boulevard,
**City**
Jiroft
**Province**
Kerman
**Postal code**
78616-15517
**Phone**
+98 34 4331 6688
**Email**
amirshekarimaryam@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Maryam Amirshekari
**Position**
University student
**Latest degree**
Bachelor
**Other areas of specialty/work**
surgery room
**Street address**
Alley 5,Pasdaran Street
**City**
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**Province**
Kerman
**Postal code**
78616-15517
**Phone**
+98 34 4331 6688
**Fax**
**Email**
amirshekarimaryam@gmail.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Maryam Amirshekari
**Position**
University student
**Latest degree**
Bachelor
**Other areas of specialty/work**
surgery room
**Street address**
Alley 5, Pasdaran Street
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**Phone**
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**Email**
amirshekarimaryam@gmail.com

## 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**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Undecided - It is not yet known if there will be 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**
Undecided - It is not yet known if there will be 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