

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 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

Isfahan

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 Amirshakari

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plate 3, 5 Pasdaran Alley, second side on the left, Pasdaran St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholam Reza Askari

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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
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Latest degree
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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

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