

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The effects of aromatherapy using rose oil (*Rosa damascena* Mill.) on preoperative anxiety: A prospective randomized clinical trial

Protocol summary

Study aim

The objective of our study is to evaluate aromatherapy with rose oil the effect on preoperative anxiety.

Design

prospective, randomized, controlled, double-blind, parallel group.

Settings and conduct

The patients who will have Septorhinoplasty operation in Ahi Evran University Training and Research Hospital Department of Otorhinolaryngology will be enrollment. The volunteers will be randomized with closed envelope method 1: 1: 1 as the control group (Group C), the sham group (Group S) and the rose oil group (Group R).

Participants/Inclusion and exclusion criteria

The patients who will have Septorhinoplasty operation in Ahi Evran University Training and Research Hospital Department of Otorhinolaryngology will be enrollment. The patients who ASA (American Society of Anesthesiologists) I-II risk group and between the ages of 18-40 will be included in the study. Hypertension, cardiac dysrhythmia, chronic depression and anxiety treatment, allergy to aromatherapy oils, bronchospasm, anosmia are exclusion criteria in this study.

Intervention groups

No application will be made in Group C (Control). In Group S (Sham), a mixture of 25 ml of 2% distilled water and glycerin will be added to the aromatherapy device. In Group R, a mixture of distilled water, glycerin and rose oil, 2% 25 ml, will be placed on the aromatherapy device.

Main outcome variables

The first STAI TX-1 (State-Trait Anxiety Inventory) (preop 1 in the clinic and preop 2 in the operating room) test will be performed by a researcher and responses will be recorded in the case report form. Heart rate, systolic-diastolic blood pressure of patients will be measured when patients arrive at the otorhinolaryngology clinic service.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180324039145N1**

Registration date: **2018-04-05, 1397/01/16**

Registration timing: **prospective**

Last update: **2018-04-05, 1397/01/16**

Update count: **0**

Registration date

2018-04-05, 1397/01/16

Registrant information

Name

Recai Dagli

Name of organization / entity

Ahi Evran University Faculty of Medicine

Country

Turkey

Phone

+90 386 213 45 15

Email address

recai.dagli@ahievran.edu.tr

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-01, 1397/03/11

Expected recruitment end date

2018-12-31, 1397/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of aromatherapy using rose oil (Rosa damascena Mill.) on preoperative anxiety: A prospective randomized clinical trial

Public title

Rose oil aromatherapy treatments for preoperative anxiety

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

The patients who will have Septorhinoplasty operation ASA (American Society of Anesthesiologists) I-II risk group Between the ages of 18-40

Exclusion criteria:

Hypertension, Cardiac dysrhythmia Chronic depression and anxiety treatment Allergy to aromatherapy oils Bronchospasm Anosmia

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Microsoft Exel random number generator function will be used with blocks of 30 for randomization as the control group (Group C), the sham group (Group S) and the rose oil group (Group R). The volunteers will be randomized with closed envelope method (number of 1-30) as 1: 1: 1 in operation morning. Randomization will be repeated every 30 patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

Heart rate, systolic-diastolic blood pressure of patients will be measured when patients arrive at the otorhinolaryngology clinic service. The first STAI TX-1 (State-Trait Anxiety Inventory) (preop 1) test will be performed by a researcher and responses will be recorded in the case report form. The patients do not know which they are groups due to closed envelop method. Aromatherapy will be implemented according to the patient's group by the care provider. The other investigator and outcome assessor will be in the operating room. In the operating room, the second STAI TX-1 test will be performed by the researcher who does not know in which group the volunteers are in the group. Preoperative heart rate, systolic-diastolic blood pressure of patients will be measured and recorded as preop 2.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ahi Evran University Clinical Investigations Ethics Committee

Street address

Bagbasi Mh.

City

Kirsehir

Postal code

40100

Approval date

2017-10-31, 1396/08/09

Ethics committee reference number

(Decision Number:2017-16-192)

Health conditions studied**1****Description of health condition studied**

Preoperative anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes**1****Description**

The first STAI TX-1 (State-Trait Anxiety Inventory) (preop 1) test will be performed by a researcher and responses will be recorded in the case report form.

Timepoint

In the operating room, the second STAI TX-1 test will be performed by the researcher who does not know in which group the volunteers are in the group.

Method of measurement

STAI TX-1 (State-Trait Anxiety Inventory) test

2**Description**

Heart rate, systolic-diastolic blood pressure of patients will be measured when patients arrive at the otorhinolaryngology clinic service.

Timepoint

In the operating room, preoperative heart rate, systolic-diastolic blood pressure of patients will be measured and

recorded as preop 2.

Method of measurement

Blood pressure using sphygmomanometer , heart rate using ECG

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: rose oil group (Group R)

Category

Treatment - Other

2

Description

Intervention group: the sham group (Group S)

Category

Placebo

3

Description

Control group: the control group (Group C)

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahi Evran University Training and Research Hospital
Department of Otorhinolaryngology

Full name of responsible person

Mehmet Metin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahi Evran University Training and Research Hospital
Department of Otorhinolaryngology

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

Ahi Evran University Training and Research Hospital
Department of Otorhinolaryngology

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Ahi Evran University

Full name of responsible person

Recai Dagli

Position

Assistant proffessor

Latest degree

Specialist

Other areas of specialty/work

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be shared by the open access manuscript. And the corresponding author can send all data or documents by e-mail.

When the data will become available and for how long

All data will be shared by the open access manuscript. And the corresponding author can send all data or documents by e-mail.

To whom data/document is available

All data will be shared by the open access manuscript.

Under which criteria data/document could be used

All data will be shared by the open access manuscript. And the corresponding author can send all data or documents by e-mail.

From where data/document is obtainable

All data will be shared by the open access manuscript. And the corresponding author can send all data or documents by e-mail.

What processes are involved for a request to access data/document

All data will be shared by the open access manuscript. And the corresponding author can send all data or documents by e-mail.

Comments

All data will be shared by the open access manuscript. And the corresponding author can send all data or documents by e-mail.