

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

The Effect of the inhalation of Lavender Essence and relaxation on the anxiety before elective gynecological surgery: A controlled randomized clinical trial.

Protocol summary

Summary

This Phase II clinical trial is conducted in order to determine the effect of lavender oil inhalation and relaxation techniques on anxiety before elective gynecologic operation. The population under study is volunteer's elective surgery women on Besat hospital in sanandaj. Based on inclusion criteria 160 samples purposefully are selected. Allocation of Samples to three intervention groups or a control group is randomly drawing a number from one to four by sealed envelope. Inclusion criteria included; elective gynecologic surgical candidates; volunteered to participate in the study; lack of underlying psychological disorders; hemodynamic stable, non-use of psychotropic medication. Exclusion criteria included Patient's withdrawal from the research, and unpredicted events before surgery. Before intervention The procedure is explained and consent was obtained from samples. Demographic data will be recorded in information sheet. The anxiety for at least two hours before surgery will be studied by , BAI questionnaire. Then the intervention is done. In the first intervention, the patient will inhale a drop of lavender essential oil. In the second intervention, For two minutes the patient is asked to be in a situation that does not feel right (seated or supine) and after a few deep breaths taken his eyes closed and his limbs were loose from the bottom up (relaxation). In the third intervention group, Inhalation of lavender oil and relaxation are combined together. In the control group, does not be intervention. Five minutes after intervention anxiety level will be studied in four groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030126861N1**

Registration date: **2016-09-09, 1395/06/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-09-09, 1395/06/19

Registrant information

Name

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Name of organization / entity

Kurdistan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Student Research Committee ,Vice chancellor for research, Kurdistan University of Medical Sciences

Expected recruitment start date

2015-09-27, 1394/07/05

Expected recruitment end date

2016-04-21, 1395/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of the inhalation of Lavender Essence and

relaxation on the anxiety before elective gynecological surgery: A controlled randomized clinical trial.

Public title

The Effect of the inhalation of Lavender Essence and relaxation on the anxiety before elective gynecological surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria included; elective gynecologic surgical candidates; volunteered to participate in the study; lack of underlying psychological disorders; hemodynamic stable (blood pressure, pulse, oxygen, respiration and body temperature and pain), non-use of psychotropic medication. Exclusion criteria included Patient's withdrawal from the research, and unpredicted events before surgery such as unstable hemodynamic status, cardiac arrest and death of patient.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 160

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj, code:66177-13446

City

Sanandaj

Postal code

6617713446

Approval date

2015-09-06, 1394/06/15

Ethics committee reference number

IR.MUK.REC.1394.165

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety NOS

Primary outcomes

1

Description

Anxiety

Timepoint

before and after intervention

Method of measurement

The anxiety for at least two hours before surgery will be studied. Five minutes after intervention anxiety level will be studied in four groups by BAI questionnaire.

Secondary outcomes

1

Description

hemodynamic status

Timepoint

before and after intervention

Method of measurement

Control pulse by touching, listening to the heartbeat, blood pressure control with manometer and pulse oximetry SPO2

Intervention groups

1

Description

intervention group1: Before surgery operating room in the reception area, A drop of lavender oil on a cotton ball will be thrown and the patient is asked to inhale it

Category

Treatment - Drugs

2

Description

intervention group2: Before surgery operating room in the reception area, for two minutes the patient is asked to be in a situation that does not feel right (seated or supine) and after a few deep breaths taken his eyes closed and his limbs were loose from the bottom up (relaxation)

Category

Prevention

3**Description**

intervention group1the patient will inhale a drop of lavender essential oil Before surgery operating room in the reception area,for two minutes the patient is asked to be in a situation that does not feel right (seated or supine) and after a few deep breaths taken his eyes closed and his limbs were loose from the bottom up (relaxation) . then , A drop of lavender oil on a cotton ball will be thrown and the patient is asked to inhale it

Category

Prevention

4**Description**

Control group: In this group there is no intervention.Routine care done before surgery

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Besat Hospital of sanandaj

Full name of responsible person

saied sina zaman

Street address

Besat Hospital, Keshavarz Street, Sanandaj

City

Sanandaj

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Student Research Committee, Vice Chancellor for research and technology of Kurdistan University of M

Full name of responsible person

Farzin Rezaee

Street address

Kurdistan University of Medical Sciences, after Qods Hospital, Pasdaran street, Sanandaj, postal code:13446-66177

City

Sanandaj

Grant name

بودجه عمومی

Grant code / Reference number

304

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

Yes

Title of funding source

Student Research Committee, Vice Chancellor for research and technology of Kurdistan University of M

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Kurdistan University of Medical Sciences

Full name of responsible person

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Position

ph.D/Assistant professor

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Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty