Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Jamal Seidi

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

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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 stabl (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
Ethic 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 groupsby 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
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Jamal Seidi
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ph.D/Assistant professor
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Person responsible for updating data

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Web page address

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