

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Effect of aromatherapy with lavender on the anxiety of patients undergoing Electro Convulsive Therapy

Protocol summary

Study aim

Determination of the effect of lavender on the anxiety level of patients treated with electro convulsive therapy

Design

Clinical trials with control group, one blind, non-randomized

Settings and conduct

In this study, all adult patients admitted to Shahid Beheshti Hospital of Kerman, who will be treated with seizure therapy, will form the study population. Patients will be divided into two groups of control and intervention by randomization method. In the intervention group, half an hour before the seizure, two drops of lavender scent will be drawn on a non-absorbent polyethylene tissue and bonded with the patient's cloth with leukoplast, and then it will be asked to stand for twenty minutes as normal breathe. In the control group, only the usual measures will be used and the anxiety of the samples before and after the intervention will be compared by a blinded fellow researcher during three sessions with the Spielberger anxiety inventory .

Participants/Inclusion and exclusion criteria

Age of over 18 years, physical health, perceived and sensory ability (eyesight, hearing, olfactory) and lack of anxiety disorders, no use of essential oils and drugs for reducing anxiety since six weeks before the intervention. no suffering from other chronic diseases such as chronic obstructive pulmonary disease. not be a student or graduated in medical sciences or psychology.

Intervention groups

Intervention group: Aromatherapy with Lavender oil.
Control group: routine care in ward.

Main outcome variables

anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170516033997N4**

Registration date: **2018-12-18, 1397/09/27**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-18, 1397/09/27**

Update count: **0**

Registration date

2018-12-18, 1397/09/27

Registrant information

Name

Tahereh Ramezani

Name of organization / entity

Kerman University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 34331325220

Email address

t_ramezani@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-01-21, 1397/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of aromatherapy with lavender on the anxiety of patients undergoing Electro Convulsive Therapy

Public title

Effect of aromatherapy with lavender on the anxiety

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients treated with Electro Convulsive Therapy(ECT)
Has awareness and insight into the disease Perceptual and sensory ability

Exclusion criteria:

Sudden onset of any serious changes in vital signs
Allergy to Lavender essential oil Patients in acute phase of psychosis Patients who received less than 3 sessions of ECT

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Investigator

Sample size

Target sample size: **110**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

Data collection is done by the researcher's colleague who does not know the group participants.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Kerman University of Medical Sciences

Street address

Somayeh Crossroads, Ethics Committee of Kerman University of Medical Sciences

City

Kerman

Province

Kerman

Postal code

7611239870

Approval date

2018-09-01, 1397/06/10

Ethics committee reference number

IR.KMU.REC.1397.193

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

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

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

Anxiety is a common, unpleasant discomfort with anxiety that results in uncertainty, frustration and physiological anxiety

Timepoint

20 minutes after intervention 3 sessions a week

Method of measurement

Spielberger Anxiety Inventory

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: aromatherapy with lavenderoil 2% Which is from Kashan Barij Essen Co. Two drops of essential oil will be dropped on a napkin and patient will breathe for twenty minutes.

Category

Prevention

2**Description**

Control group: In the control group, routine actions are performed before the ECT

Category

Prevention

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

Shahid Beheshti Hospital in Kerman

Full name of responsible person

Tahere Ramezani

Street address

Islamic Republic Boulevard, Shahid Beheshti Hospital

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Fax**Email**

beheshticms@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

Street address

Vice Chancellor for Research and Technology, Kerman University of Medical Sciences, Street Ibn Sina, Tahmasebabad Crossroads.

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vcf@KMU.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

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**

Kerman University of Medical Sciences

Full name of responsible person

Tahereh Ramezani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Because of the confidentiality of patient information

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