Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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Kerman University of Medical Science
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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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
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Abbas Pardakhty
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Vice Chancellor for Research and Technology, Kerman University of Medical Sciences, Street Ibn Sina, Tahmasebabad Crossroads.
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7616913555
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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
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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