

# 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

**City**

Kerman

**Province**

Kerman

**Postal code**

7613747181

**Phone**

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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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Kerman

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7616913555

**Phone**

+98 34 3132 5820

**Email**

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

**Street address**

Kerman University of Medical Sciences Campus , beginning around Seven Alavi Garden, Kerman

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**Email**

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## Person responsible for scientific 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.

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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