

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### The effect of lavender aromatherapy on anxiety and cognitive status of patients undergoing electroconvulsive therapy in 5 Azargargan hospital in 2022

#### Protocol summary

##### Study aim

The effect of lavender aromatherapy on anxiety and cognitive status of patients undergoing electroconvulsive therapy in 5 Azargargan hospital in 2022

##### Design

Clinical trial with intervention and control group, with parallel groups, single-blind, randomized, phase 3 on 80 patients. Randomization of data analysis will be done using SPSS-16.

##### Settings and conduct

Method : 80 ECT candidate patients are divided into two groups of test and control and homogenized in terms of number, age, and sex. The data collection tool will include a checklist of demographic characteristics, the Montreal Cognitive Test (MoCA) and Beck's anxiety questionnaire. One hour before ECT, the questionnaires are completed by the intervention and control groups. For 10 to 20 minutes, sterile gas containing five drops of lavender essential oil in the test group, and the same amount of placebo (distilled water) in the control group, will be placed in front of the nose of the samples to inhale. One hour after receiving ECT, when the samples are in a state of consciousness and proper orientation to time, place and person, the questionnaires will be completed again.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: Hospitalized patients with ECT indication based on DSM-5 criteria, positive smell test, satisfaction with participating in the study, ability to verbally communicate with researchers, age 25-55 years, at least literate exclusion criteria: History of serious medical diseases such as hyperthyroidism, concomitant serious psychiatric diseases. Withdrawal from the study, having an allergy to lavender during the intervention, decreased level of consciousness.

##### Intervention groups

Intervention and control group

#### Main outcome variables

Lavender aromatherapy, anxiety, cognitive status, age, gender, level of education, marital status.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220915055965N1**

Registration date: **2022-12-04, 1401/09/13**

Registration timing: **prospective**

Last update: **2022-12-04, 1401/09/13**

Update count: **0**

##### Registration date

2022-12-04, 1401/09/13

##### Registrant information

##### Name

Mohammadzaman Kamkar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3115 3365

##### Email address

kamkar72@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-12-06, 1401/09/15

##### Expected recruitment end date

2023-03-03, 1401/12/12

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of lavender aromatherapy on anxiety and cognitive status of patients undergoing electroconvulsive therapy in 5 Azargorgan hospital in 2022

**Public title**

the effect of lavender on anxiety and cognition

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Admitted to the psychiatric department, all patients with ECT indication based on DSM-5 criteria with the diagnosis of a psychiatrist, consent to participate in the study, the ability to verbally communicate with the researchers, aged 25 to 55 years, patients benefit from minimal reading and writing literacy. (Middle or 8th grade), do not have any disease or physical disability such as speech, hearing or vision impairment, a positive smell test (olfactory nerve health test) is taken from them in such a way that the coffee sample is taken under their nose with their eyes closed and smell it), have no history of physical problems that lead to cognitive disorders such as mental retardation, epilepsy, dementia, and head trauma, no physical diseases related to anxiety and cognitive disorders such as pheochromocytoma, thyroid problems, and brain tumors, no bad Consuming alcohol and drugs, not taking anti-anxiety drugs, being aware of the time and place before the electroshock, having the physical and mental ability to answer questions, not having a history of allergies and respiratory diseases, schizophrenic patients who are dominated by negative symptoms and their reality check is impaired. are not eligible to enter the study.

**Exclusion criteria:**

Patients who have difficulty communicating verbally, withdraw from the study, have an allergy to lavender during the intervention, decrease the level of consciousness of the patient during the study, participate in other studies that affect their anxiety and cognitive status.

**Age**

From **25 years** old to **55 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The present study will be conducted in order to investigate the effect of lavender aroma therapy on the anxiety and cognitive status of patients undergoing electroshock therapy in the fifth hospital of Azargorgan in 1401. After approving and receiving the code of ethics from the University of Medical Sciences, and obtaining permission from the authorities of 5 Azar Gorgan Hospital, the research will begin. This study is a clinical trial study, the number of 80 patients under treatment with ECT was selected using the available sampling method, and then based on simple random assignment, they were divided equally into two test and control groups (40 people in each group) and considering equalization in terms of number, age, and gender. They will be. The samples are equally selected from patients with bipolar disorder. After explaining the objectives of the study and how to complete the questionnaires to the research samples and assuring them about the confidentiality of the answers, the researcher first obtains informed written consent from them and then the questionnaires are completed by them. The data collection tool in this study will include demographic characteristics checklist, Montreal Cognitive Assessment (MoCA) and Beck's anxiety questionnaire. The samples will be selected considering the entry and exit criteria. The method of conducting the intervention will be that one hour before ECT, the Beck questionnaire will be completed to measure anxiety, and the MoCA questionnaire will be completed by the intervention and control groups to measure their cognitive status. Lavender drops made in Iran by Zarband company will be used. In the test group, for 10 to 20 minutes, sterile gas containing five drops of lavender essential oil, and the same amount of placebo (distilled water) in the control group, will be placed in front of the nose of the samples to inhale. One hour after receiving ECT, when the samples are in a state of consciousness and proper orientation to time, place and person, they will complete the questionnaires once again. And finally, the data will be collected and analyzed in different groups. Data analysis will be done using SPSS-16.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

To avoid bias, neither the researchers nor the patients know which drops are used, and for this purpose, the research colleagues simultaneously and separately, one person in the intervention group and the other in the control group, conduct the research.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Golestan University of Medical Science

**Street address**

5 azar ave., 5 azar hospital

**City**

Gorgan

**Province**

Golestan

**Postal code**

4917763681

**Approval date**

2022-07-03, 1401/04/12

**Ethics committee reference number**

IR.GOUMS.REC.1401.155

## Health conditions studied

### 1

**Description of health condition studied**

Bipolar disorder

**ICD-10 code**

F31

**ICD-10 code description**

Bipolar disorder

## Primary outcomes

### 1

**Description**

Anxiety before and after the intervention

**Timepoint**

One hour before and one hour after electroconvulsive therapy

**Method of measurement**

Based on the average scores obtained from Beck Anxiety inventory and Montreal Cognitive Assessment (MOCA)

### 2

**Description**

Cognitive status before and after the intervention

**Timepoint**

One hour before and one hour after electroconvulsive therapy

**Method of measurement**

Beck Anxiety Questionnaire and Montreal Cognitive Assessment (MOCA)

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: The method of conducting the intervention will be that one hour before ECT, the Beck questionnaire will be completed to measure anxiety, and the MoCA questionnaire will be completed by the intervention group to measure cognitive status. Sterile gas containing five drops of lavender essential oil made in Iran, Zarband company, will be placed in front of the nose of the samples for 10 to 20 minutes to inhale. One hour after receiving ECT, when the patients are in a state of consciousness and proper orientation to time, place and person, they will complete the questionnaires again.

**Category**

Treatment - Drugs

### 2

**Description**

Control group: One hour before ECT, the Beck questionnaire to measure anxiety, and the MoCA questionnaire to measure cognitive status, will be completed by the control group. Gas impregnated with five drops of sterile distilled water (placebo) will be placed in front of the nose of the samples to inhale. One hour after receiving ECT, when the patients are in a state of consciousness and proper orientation to time, place and person, they will complete the questionnaires again.

**Category**

Placebo

## Recruitment centers

### 1

**Recruitment center****Name of recruitment center**

5 azar hospital of Gorgan

**Full name of responsible person**

Mohammad Zaman Kamkar

**Street address**

5 azar ave., 5 azar hospital

**City**

Gorgan

**Province**

Golestan

**Postal code**

4917763681

**Phone**

+98 17 3115 3365

**Email**

kamkar72@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Mohammad Zaman Kamkar

**Street address**

5 azar ave., 5 azar hospital

**City**

Gorgan

**Province**

Golestan

**Postal code**

4917763681

**Phone**

+98 17 3115 3365

**Email**

kamkar72@yahoo.com

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Gorgan 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**

Gorgan University of Medical Sciences

**Full name of responsible person**

Mohammad Zaman Kamkar

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

5 azar ave., 5 azar hospital

**City**

Gorgan

**Province**

Golestan

**Postal code**

4917769681

**Phone**

+98 17 3115 3365

**Email**

kamkar72@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Mohammad Zaman Kamkar

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

5 azar ave., 5 azar hospital

**City**

Gorgan

**Province**

Golestan

**Postal code**

4917763681

**Phone**

+98 17 3115 3365

**Email**

kamkar72@yahoo.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Mohammadzaman Kamkar

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

5azar Ave., 5azar hospital,

**City**

Gorgan

**Province**

Golestan

**Postal code**

4917763681

**Phone**

+98 17 3115 3365

**Fax**

**Email**

kamkar72@yahoo.com

## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The individual data of the participants without mentioning their names, as well as the results of the research, can be made available to researchers after public publication and with the permission of the university's ethics committee.

**When the data will become available and for how long**

After public release through the article.

**To whom data/document is available**

All researchers

**Under which criteria data/document could be used**

For additional research work

**From where data/document is obtainable**

Conductors of the research

**What processes are involved for a request to access data/document**

Request from the administrator and the reason for the request, obtaining the permission of the administrator from the ethics committee of the university. Corresponding author's email: kamkar72@yahoo.com

**Comments**

We have not started sampling, we need to get a code from IRCT to take samples.