

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the Effect of Melissa Officinalis L ( Lemon Balm) Capsule on Cognitive Impairment in Depressed Patients Treated With ECT

#### Protocol summary

##### Study aim

Determining the effect of Lemon Balm Capsule on Cognitive Disorders in Depressed Patients treated with ECT

##### Design

Sampling will first be done in an accessible way that all hospitalized patients who met the study conditions will be included in the study. Random allocation of people to two groups will be done by randomization of permutation blocks and using software, random allocation

##### Settings and conduct

Necessary referral letters will be provided to the psychiatric ward of Hajar Hospital and after sampling through random allocation, they will be placed in intervention and control groups. The Study is a Blind One-Way study in which data analysts do not know about the drug used

##### Participants/Inclusion and exclusion criteria

Participants in this study were 80 patients treated with ECT Inclusion Criteria: The age range of patients is 18-65 years; their Major Depressive Disorder has been confirmed by a psychiatrist; the patient has no history of allergy to the mint family; lack of physical illness leading to Cognitive Impairment such as Head Trauma, Dementia, Retardation-Mental Retardation and Epilepsy; patients receiving SSRIs (according to a psychiatrist). Exclusion Criteria: Patients who have other Mental Disorders in addition to Depression; reluctance to continue cooperation before the end of the project; occurrence of stressful events affecting the Patient's mood during the implementation of the plan; use of other Antidepressants Drugs (except SSRIs)

##### Intervention groups

The two groups of 40 people, including the intervention and control groups, will use 500 mg of Lemon Balm capsules in the intervention group and 500mg of starch capsules in the control group.

##### Main outcome variables

Improves Post-ECT Amnesia

#### General information

##### Reason for update

Increasing the number of samples

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180613040083N1**

Registration date: **2022-06-10, 1401/03/20**

Registration timing: **prospective**

Last update: **2022-10-07, 1401/07/15**

Update count: **2**

##### Registration date

2022-06-10, 1401/03/20

##### Registrant information

##### Name

Fatemeh Kaviani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 3338 8836

##### Email address

fatemeh.kaviani950@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-10-22, 1401/07/30

##### Expected recruitment end date

2022-11-21, 1401/08/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Evaluation of the Effect of Melissa Officinalis L ( Lemon Balm) Capsule on Cognitive Impairment in Depressed Patients Treated With ECT

## Public title

Evaluation of the Effect of Melissa Officinalis L ( Lemon Balm) Capsule on Cognitive Impairment in Depressed Patients Treated With ECT

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

The age range of patients is 18-65 years. Their Major Depressive Disorder has been confirmed by a psychiatrist. The patient has no history of allergy to The mint family. Lack of physical illness leading to Cognitive Impairment such as Head Trauma, Dementia, Retardation - Mental Retardation And Epilepsy. Patients Receiving SSRIs (according to a psychiatrist).

### Exclusion criteria:

Patients who have other Mental Misorders in addition to Depression.. Reluctance to continue cooperation before The end of the project Occurrence of stressful events affecting The patient's mood during the implementation of The plan Use of other Antidepressants Drugs(except SSRIs)

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Data analyser

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

To randomly assign individuals to two groups, using the randomization Replacement blocks method were used. By using the software, a random block of fifteen blocks with a volume of six was designed and a randomization list was provided to the researchers. In each of the 70 blocks are written two letters, a, two letters b, a which means intervention group and b means control group

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The study is a double-blind study, in which the project implementer and the patients are not aware of the process and drugs, and the data analyst is not aware of the drug used.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

##### Street address

Kashani St., Shahrekord University of Medical Sciences, Ethics Committee of Shahrekord University of Medical Sciences

##### City

Shahrekord

##### Province

Chahar-Mahal-va-Bakhtiari

##### Postal code

8815713471

#### Approval date

2021-06-08, 1400/03/18

#### Ethics committee reference number

IR.SKUMS.REC.1400.074

## Health conditions studied

### 1

#### Description of health condition studied

Major Depression , ECT

#### ICD-10 code

F99

#### ICD-10 code description

Mental disorder, Not Otherwise Specified

## Primary outcomes

### 1

#### Description

Cognitive Disorders Score in Cognitive Status Assessment Questionnaire (MMSE Questionnaire)

#### Timepoint

Measurement of Cognitive Disorders before intervention and one month after consumption of Lemon Balm Capsules

#### Method of measurement

Cognitive Status Assessment Questionnaire (MMSE Questionnaire)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 40 depressed patients treated with ECT, receiving 500mg lemon balm capsules (made by the Made by a pharmacist) every 8 hours after a month Evaluation with questionnaire

**Category**

Treatment - Drugs

**2****Description**

Control Group: 40 depressed patients treated with ECT, receiving 500mg placebo capsules (made by the Made by a pharmacist) every 8 hours after a month Evaluation with questionnaire

**Category**

Treatment - Drugs

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

Hajar Hospital in Shahrekord

**Full name of responsible person**

Majid Taheri

**Street address**

Hajar Hospital , Parastar St.

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8817917546

**Phone**

+98 38 3338 8836

**Email**

Info@Skums.ac.ir

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Dr. Esfandiar Heydarian

**Street address**

Shahre-kord University of Medical Sciences , Kashani St .

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**Province**

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

Yes

**Title of funding source**

Shahre-kord University of Medical Sciences

**Proportion provided by this source**

50

**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**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Dr. Massoud Nikfarjam

**Position**

Psychiatrist

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

**Street address**

Hajar Hospital, Parastar St.

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Dr. Massoud Nikfarjam

**Position**

Psychiatrist

**Latest degree**

Specialist

**Other areas of specialty/work**

Psychiatrics

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FatemeKaviani950@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Fatemeh Kaviani

**Position**

Nurse

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No.12 Jihad Alvand St, Mirabad West

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**Province**

Chahar-Mahal-va-Bakhtiari

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

Undecided - It is not yet known if there will be a plan to make this available

**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