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 psychiatrists; 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
ImprovesPost-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 EpilepsyPatients 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 pharmacologist) 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 pharmacologist) 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
Shahrekord University of Medical Sciences , Kashani St .

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713471

Phone
+98 38 3333 0061

Email
Pajoohesh@Skums.ac.ir

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.

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8815713471

Phone
+98 38 3333 0061

Email
Nikmas140@gmail.com

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

Street address
Hajar Hospital, Parastar St.

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3333 0061
Email
Nikmas140@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
City
Shahrekord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8817917546
Phone
+98 38 3338 8836
Email
FatemeKaviani950@gmail.com

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