Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Augmenting Modafinil to Escitalopram on Depressive, Cognitive and Fatigue Symptoms in Patients with Post-Stoke Depression:A Randomized, Double-blind, Placebo-Controlled Clinical trial

Protocol summary

Study aim

Investigating the status of depressive and cognitive and fatigue symptoms in patients with post stroke depression in the modafinil and citalopram group compared to the citalopram and placebo group

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase three, on 66 patients with post stroke depression are divided into two groups of 33 people by lottery

Settings and conduct

Patients visiting the neurology clinic and patients admitted to the stroke department of Rofeideh Rehabilitation Hospital with Post-Stroke Depression randomly divided into two groups and random codes will be assigned to them. One group Modafinil and Escitalopram and the other group will receive placebo and Escitalopram daily for 6 weeks; Medicines with a similar appearance and coded that only the manufacturing company and the analyzing person are aware of the distribution method, none of the plan executive, researcher, patients and drug distributor till the end of the study, will not be informed about the concept of codes. Before the start and every two weeks afte start symptoms are checked with relevant tests.

Participants/Inclusion and exclusion criteria

Inclusion criteria are age above 20 years, the diagnosis of post-stroke depression,which also has symptoms of fatigue and cognitive impairment, reading and writing literacy,and the conditions for not entering are a history of depression, dementia, other psychiatric diseases, the presence of a disease with fatigue as a proven manifestation before stroke, pregnancy or the desire to become pregnant, breastfeeding and the presence of contraindications for taking Escitalopram or Modafinil

Intervention groups

66 patients with post-stroke depression will be included in the two groups of intervention group Ecitalopram and modafinil and the control group Ecitalopram and modafinil

Main outcome variables

Depression; Cognition; Fatigue

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231106059971N1**
Registration date: **2024-01-09, 1402/10/19**
Registration timing: **prospective**

Last update: **2024-01-09, 1402/10/19**
Update count: **0**

Registration date

2024-01-09, 1402/10/19

Registrant information

Name

Nazila Jabbari Nejad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-10, 1402/10/20

Expected recruitment end date

2025-01-09, 1403/10/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect of Augmenting Modafinil to Escitalopram on Depressive, Cognitive and Fatigue Symptoms in Patients with Post-Stoke Depression:A Randomized, Double-blind, Placebo-Controlled Clinical trial

Public title
The Effect of Augmenting Modafinil to Escitalopram on Depressive, Cognitive and Fatigue Symptoms in Patients with Post-Stoke Depression
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients'age must be older than 20 years. ischemic stroke or intracerebral hemorrhage at least 21 days after cerebrovascular accident. Modified Rankin Scale (MRS) score must be 3 or less. Consent to participate in the study. Having a diagnosis of post-stroke depression with a HAM-D score above 8. The patients must be literate. MoCA must be above 18. Constant fatigue reported by the patient with an MFI-20 score equal to 12 or more.
Exclusion criteria:
History of depression, dementia or other psychiatric diseases before stroke Having other diagnoses with fatigue as a known symptom Use of Benzodiazepines or Antiepileptic drugs History of other brain diseases or trauma within 30 days before screening Pregnancy or intention to become pregnant, breastfeeding
Age
From **20 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling by lottery (names of patients are written on a paper and placed in a box, then the papers are removed one by one until the sample size of the desired group is complete) will be divided into two groups: Placebo plus Escitalopram group: This group will receive placebo and oral Escitalopram (10 mg daily) for 6 weeks. Modafinil plus Escitalopram group: These patients will receive Modafinil (200 mg daily) and oral Escitalopram (10 mg daily) for 6 weeks.
Blinding (investigator's opinion)
Double blinded
Blinding description
In the Double-Blind method the Patient, Researcher, Evaluator and The threated Group are all independent of each other and neither will be informed of the patients groups and their medications. According to random numbers which given to each individual, patients will divided into two groups; The Treated group With Escitalopram and Modafinil (Intervention group) and Placebo and Escitalopram group (Control group) and each Group will assigned a code with which the main drugs and placebo are coded and are provided in the same package to each group and only at the end of the study, when interpreting the data, the codes will be identifiable to the Researcher and Evaluator in order to access the subgroup related to each code (Intervention group or Control group). Until then, Only the Analyst and Drug manufacturer will know how the people in each group are distributed and the concept of the code which assigned to each group. Participants are aware that they are participating in the study and will be given an informed consent form to participate; but will not be aware of the type of medication they took until the end of the study.A person in the ward Nursing staff, who is outside the research team, is used to distribute the medicine; This person also does not know about the assignment of groups and distributes medicines among the candidates based on these codes. Also, due to the use of placebo with the same Color and taste, the type of drug can not be distinguished from the main drug. The only exception to breaking the code is the occurrence of complications that require each subject to know the type of drug, in which case how to do it and the person who can break the code is clear; and this person will not be the main researcher or evaluator, The patient will also be excluded from the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of the University of Social Welfare and Rehabilitation sciences
Street address
Kodakyar Ave., Daneshj Blvd., Evin
City
Tehran
Province
Tehran
Postal code

1985713834

Approval date

2023-09-27, 1402/07/05

Ethics committee reference number

IR.USWR.REC.1402.152

Health conditions studied

1

Description of health condition studied

Post-Stroke Depression

ICD-10 code

F06.31

ICD-10 code description

Mood disorder due to known physiological condition with depressive features

Primary outcomes

1

Description

Depression score in Hamilton Depression Rating Scale

Timepoint

At the beginning of the study and 2, 4 and 6 weeks after the start of the intervention

Method of measurement

Depression score in Hamilton Depression Rating Scale

2

Description

Fatigue score in Fatigue Severity Scale

Timepoint

At the beginning of the study and 2, 4 and 6 weeks after the start of the intervention

Method of measurement

Fatigue Severity Scale

3

Description

Cognitive function score in Montreal Cognitive Assessment

Timepoint

At the beginning of the study and 2, 4 and 6 weeks after the start of the intervention

Method of measurement

Montreal Cognitive Assessment

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 33 patients diagnosed with Post-Stroke Depression are given 5 mg of Escitalopram, and if there are no side effects, it is increased to 10 mg after two weeks, they are also given 100 mg of modafinil, which is if there are no side effects after two weeks, it is increased to 200 mg and two drugs are continued for 6 weeks. Control group: Another 33 patients diagnosed with Post-Stroke Depression were given 5 mg of Escitalopram, which was increased to 10 mg after two weeks if there were no side effects, and they were also given a placebo, which both medications will be continued for 6 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofeideh rehabiliation hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

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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
University of social welfare and rehabilitation 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
University of social welfare and rehabilitation sciences

Full name of responsible person
Nazila Jabbari Nejad

Position
Non-faculty specialist doctor

Latest degree
Specialist

Other areas of specialty/work
Psychiatrics

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Unit 172., Kosar Complex., Pas Farhangian Alley., Northern Etaati St., Marzdaran Blvd

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Position
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable

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

Title and more details about the data/document

Participants' data file :After unrecognizabling the individuals ,the section on the main outcome and results of the study will be published and other information will be kept by the researcher and will be available to other researchers if needed. Study protocol: How to do the study in detail will be published .Informed consent form :The raw form will be published ,but the form related to each patient can not be published due to the fact that it contains the patient's name and some personal information ,but will remain with the researcher Clinical study report :The result of the study will be published in a transparent manner along with the result of statistical analysis.

When the data will become available and for how long

6 months after the end of the study and the final analysis ,the initial information will be published.The final results will be available at the same time as the results are published.

To whom data/document is available

Access to the dissertation is based on the university mechanism and the rules of the educational center and is available for academic and scientific institutions.If the article is published,the results will be available to the public.(subject to the rules of the relevant journal)

Under which criteria data/document could be used

Access to non-personally identifiable data and other documents is under the supervision of the University Ethics Committee,and at its discretion the authority will have limited access to additional research.

From where data/document is obtainable

University of Rehabilitation and Social Health

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

Referral to the University of Rehabilitation and Social Health, review of the application by the ethics committee,review of the application by the graduate unit,if approved by the university, as well as obtaining approval and consent from the lead researcher regarding the use of data in another study, documents will be available.

Comments