Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of the Effectiveness of Antidepressant Agents, Venlafaxine Versus Sertraline in Patients with Epilepsy and Depression

Protocol summary

Study aim
Comparing therapeutic effects of venlafaxine and sertraline on depressive symptoms, the number of seizures, and quality of life in patients with epilepsy

Design
Two arm parallel group, concealed, randomized clinical trial. Each parallel group includes 15 patients with epilepsy and associated depression. rand function will be used on excel for randomization. It is a phase 2 trial.

Settings and conduct
A hospital clinic has been chosen for the selection, treatment allocation of patients, and before and after evaluation procedures. These steps will be conducted using a screening questionnaire, clinical interview based on the Hamilton depression scale, and allocation to one of the two parallel treatment groups.

Participants/Inclusion and exclusion criteria
18 to 75 years old patients with a definite diagnosis of epilepsy by a certified neurologist who acquire the clinical diagnostic criteria of depression based on the NDDI-E questionnaire and Hamilton depression clinical scale

Intervention groups
This study has two intervention groups (1 and 2), including patients with epilepsy and in whom the symptoms of depression have been evaluated. Group 1 will be given venlafaxine at a specific dose and gradually increasing the dose to 37.5, 75, and 150 ml for the first, second, and subsequent weeks, respectively. Group 2 will also be given sertraline at a specific dose and gradually increasing the dose to 25, 50, and 100 ml for the first, second, and subsequent weeks, respectively

Main outcome variables
Evaluation of changes in signs and symptoms of depression associated with epilepsy; Changes in the number of seizures following possible control of depression; Evaluation of changes in quality of life with the possible reduction of depressive symptoms following the effectiveness of drug treatment

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210608051515N2**
Registration date: **2021-07-18, 1400/04/27**
Registration timing: **prospective**

Last update: **2021-07-18, 1400/04/27**
Update count: **0**

Registration date
2021-07-18, 1400/04/27

Registrant information

Name
Seyyed Reza Ebadi

Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-21, 1400/04/30

Expected recruitment end date
2021-08-21, 1400/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Evaluation of the Effectiveness of Antidepressant Agents, Venlafaxine Versus Sertraline in Patients with Epilepsy and Depression

Public title

Comparison of Venlafaxine and Sertraline Therapeutic Effects on Depression in Patients with Epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definite Diagnosis of Epilepsy based on Clinical Findings and Neurologist View Positive Evaluation of Depression based on NDDI-E Questionnaire Clinical Diagnosis of Moderate to Severe Depression Using Hamilton Depression Scale

Exclusion criteria:

Suicide Attempt in Recent Year Alcohol or Substance Abuse History of a Complex Mood Disorder e.g. Bipolar Disorder Other Accompanying Neurological Disease Evidence of Hypersensitivity to SSRIs Hypertension Major Kidney or Liver Dysfunction Active Hemorrhage Pregnancy and Breast-feeding

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in accordance with allocation concealment will be done by generating random codes - consisting of three characters of English letters and numbers - generated using a web resource (here at random.org), then printing the codes on a card, and placing each card in a sealed envelope. (SNOSE method). (The list of these codes will be available only to the investigator who will not intervene in any other part of the study.) Fifteen codes will be generated for intervention group 1 (Venlafaxine) and another fifteen codes for intervention group 2 (Sertraline). These codes are written on the cards to be inserted into the envelopes. Each code is placed in an opaque envelope with an aluminum inner lining; then, the envelope lid will be completely sealed. (All of the above arrangements will be made by the same person who has the list of codes and is responsible for transferring the drugs into the envelope-shaped drug container - in the same shape, color, and containing the same number of tablets for intervention group 1 and 2 - which is used to deliver the drug to patients). Sealed envelopes containing coded cards will be shuffled; each will be numbered from 1 to 30 and placed in a box handed over to another researcher responsible for delivering the drugs to the participants. Finally, the patients who will be referred to the order will be given a numbered envelope out of the box; the envelope seal will be is broken, the drug number 1 or 2 envelope-like container (anonymous for both the researcher and the patient) will be delivered to the patient according to the code on the card, his details are written on the envelope also in a separate list. In that list, each patients' name will be written in front of their envelope code. Thus, in subsequent visits (weeks 3, 8, and 16), while assessing clinical changes, the delivery of paper envelope-like containers including the first or second intervention drug (venlafaxine or sertraline) is done based on the patient's code. The researcher delivers drugs to the patients, and the patient does not know the type of intervention. (It is emphasized that the production of codes and the allocation of half of the codes to intervention 1 and the other half to intervention 2 is done by another researcher who has no responsibility in this or other stages of the study)

Blinding (investigator's opinion)

Triple blinded

Blinding description

Study participants will all be unaware of the group they will be allocated to (intervention 1 or intervention 2). However, they are aware that they will participate in a study that they will be given either venlafaxine or sertraline. Also, due to the coded label and the same specifications on the envelope containing drugs 1 and 2, blinding is done as much as possible. However, because the two drugs used in the study will not be the same in terms of color, odor, shape, and size (due to the impossibility of this task to us), blinding will not be completely feasible. Clinical caregivers, researchers, and physicians responsible for diagnosis and treatment will all be unaware of the treatment assigned to the person being examined. Those responsible for evaluating the results will also evaluate and analyze the statistical analysis of the data through coding done for patients, without knowing the patient group - Drug 1 or Drug 2. The Data Safety and Monitoring Committee also monitors the identities of people who have received the drug or placebo and their identities and only monitors the above in accordance with blinding, concealment, and data collection protocols.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences,

Street address

Room 605، Secretariat of the Ethics Committee in University Biomedical Research، Vice Chancellor for Research and Technology, 6th Floor, Central University Organization, Corner of Ghods St., Keshavarz Blvd.

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Province

Tehran

Postal code

1417653761

Approval date

2021-06-13, 1400/03/23

Ethics committee reference number

IR.TUMS.IKHC.REC.1400.081

Health conditions studied

1

Description of health condition studied

Depressive Disorders

ICD-10 code

F06.31

ICD-10 code description

Mood disorder due to known physiological condition with depressive features

2

Description of health condition studied

Epilepsy

ICD-10 code

G40

ICD-10 code description

Epilepsy and recurrent seizures

Primary outcomes

1

Description

The severity of depression in patients with epilepsy participating in the study according to the Hamilton scale

Timepoint

Depression severity at the beginning of the study (before the intervention), the third, eighth, and sixteenth weeks after the intervention is evaluated.

Method of measurement

Hamilton depression clinical scale (HAM-D)

Secondary outcomes

1

Description

Number of seizures that occur during the week (if any)

Timepoint

At the beginning of the study (before the intervention) and then the third, eighth, and sixteenth week after the intervention

Method of measurement

Counting the number of seizures per week based on history

2

Description

Quality of Life in Epilepsy

Timepoint

Before initiating the therapy and after sixteen week of treatment

Method of measurement

Quality of Life in Epilepsy (31 Questions) Questionnaire

3

Description

Pharmacological side effects

Timepoint

In the first week and then the third and eighth after the intervention

Method of measurement

Based on the history and a prepared form of drug side effects

Intervention groups

1

Description

Intervention group 1: venlafaxine; Drug therapy started with 37.5 mg in the first week, reached 75 mg in the second week and finally reached 150 mg in the third week to the sixteenth week.

Category

Treatment - Drugs

2

Description

Intervention group 2: Sertraline; Drug therapy in this group starts with 25 mg in the first week, reaches 50 mg in the second week, and is finally 100 mg in the third week to the sixteenth week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran, Imam Khomeini Hospital Complex

Full name of responsible person

Abbas Tafakhori

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Epilepsy Clinic, First Floor, Center of Neurological Diseases Research Building, Imam Khomeini Hospital Complex, Baqer Khaan Ave., Chamraan Highway, Tehran, Tehran

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Sponsors / Funding sources

1

Sponsor

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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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Seyyed Reza Ebadi

Position
Physician Researcher

Latest degree
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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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available