Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jul 2026

The evaluation of effectiveness of Adjunctive use of sertraline on seizure improvement in patients with drug-resistant temporal lobe epilepsy

Protocol summary

Study aim
The effectiveness of adjunctive use of Sertraline in patients with drug-resistant temporal lobe epilepsy who referred to Emam Reza Clinic- Shiraz-Iran

Design
Phase two clinical trial as an open-label pilot study without control group on 30 patients

Settings and conduct
30 patients will be enrolled with convenience sampling from Comprehensive Epilepsy Center at Shiraz University of Medical Sciences. In the first visit, signing of informed consent, enrollment and registration, baseline Beck Depression inventory assessment, Beck Anxiety inventory assessment, and suicidal of the patients will be documented. In the second visit (8 week baseline), seizure types (focal seizures with impaired awareness and focal to bilateral tonic-clonic seizures), seizure count, and suicidality of the patients weill determine. In this visit, all eligible patients receive oral Sertraline as 25mg on a daily from day 1 to 7 (titration period), and then 50 mg daily from day 8-63, and finally, 50 twice per day for the rest of the study period. All patients will follow for 16 weeks after their titration period. The previously prescribed AEDs will continue during the study with doses similar to the baseline evaluation period. Follow up visits will schedule at 9th and 18th weeks to determine the seizure types and seizure count and also to determine the safety and tolerability of adjunctive use of Sertraline, and suicidality in these patients. At the end of the study, all patients will assess by BDI and BAI again.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients with drug-resistant temporal lobe epilepsy, between ages 18 and 65 years. Exclusion criteria: patients with progressive neurological conditions psychogenic seizures suicidal attempt in the past five years any contraindication for sertraline administration

Intervention groups
All eligible patients

Main outcome variables
Seizure count

General information

Reason for update
This clinical trial has yet to begin due to the covid pandemic. And, hopefully, this will begin when the Covid epidemic has ended.

Acronym
monoamine oxidase inhibitors (MAOIs); antiepileptic drugs(AEDs); Beck Depression inventory (BDI); Beck Anxiety inventory (BAI)

IRCT registration information
IRCT registration number: **IRCT20200517047483N1**
Registration date: **2020-08-21, 1399/05/31**
Registration timing: **prospective**

Last update: **2022-02-18, 1400/11/29**
Update count: **1**

Registration date
2020-08-21, 1399/05/31

Registrant information

Name
Mahtab Rostamhosseinkhani
Name of organization / entity
Country
Iran (Islamic Republic of)
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Email address
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-30, 1401/07/08

Expected recruitment end date

2023-03-06, 1401/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The evaluation of effectiveness of Adjunctive use of sertraline on seizure improvement in patients with drug-resistant temporal lobe epilepsy

Public title
The evaluation of effectiveness of Adjunctive use of sertraline on seizure improvement in patients with drug-resistant temporal lobe epilepsy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Male / female (non-pregnant female adequately protected from conception) patients, between ages 18 and 65 years Patients with diagnosis of temporal lobe epilepsy The patient made on the basis of clinical findings with drug-resistant seizures defined as failure of two or more AEDs at maximal tolerated doses and one or more seizures per month The patients have stable medication regimen for four weeks prior to entry

Exclusion criteria:
Patients with progressive neurological conditions Patients with a history of non adherence for seizure diary completion or frequent clinic visits Patients with a history of having any serious medical illness or major psychiatric disorder, History of psychogenic nonepileptic seizures History of suicidal attempt in the past five years any known Pracense of contraindication for sertraline administration including: concomitant use in patients taking monoamine oxidase inhibitors (MAOIs) and hypersensitivity to sertraline Taking any other medication with significant drug interaction with sertraline

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features
This is an open-label pilot study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Medical Sciences Review Board and Ethics Committee (IRCT)

Street address
Namazi Sq., Zand St.

City
Shiraz

Province
Fars

Postal code
7193613311

Approval date
2020-01-21, 1398/11/01

Ethics committee reference number
IR.SUMS.MED.REC.1398.577

Health conditions studied

1

Description of health condition studied
Temporal lobe epilepsy

ICD-10 code
G40.01

ICD-10 code description
Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable

Primary outcomes

1

Description
The effect of Sertraline on reducing of seizure count in patients with drug-resistant temporal lobe epilepsy

Timepoint
Before starting the study, 9th & 18th weeks of study, at the end of the study

Method of measurement
History taking

2

Description
The effect of Sertraline on reducing of depression rate in patients with drug-resistant temporal lobe epilepsy

Timepoint
Before starting the study, at the end of the study

Method of measurement

Beck Depression Inventory Assessment

3

Description
The effect of Sertraline on reducing of anxiety rate in patients with drug-resistant temporal lobe epilepsy
Timepoint
Before starting the study, at the end of the study
Method of measurement
Beck Anxiety Inventory Assessment

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:the patient with drug-resistant temporal lobe epilepsy. Drug name: Sertraline; Brand: Asentra; Manufactured by: Actoverco under license Krka; Ingredients: Each coated tablet contains 50 mg or 100 mg of Sertraline Hydrochloride; other ingredients: Calcium Hydrogen Phosphate Dihydrate, Sodium Starch Glycolate, Microcrystalline Cellulose, Hydroxypropyl Cellulose, Talc, Magnesium Stearate, Hydroxypropyl Methyl cellulose, Titanium Dioxyl (Titanium dioxyl). In the second visit (8 week baseline), all eligible patients receive oral Sertraline as 25 mg on a daily from day 1 to 7 (titration period), and then 50 mg daily from day 8-63, and finally, 50 twice per day for the rest of the study period. How to use: The drug should be taken every day at certain times, with or without food. The drug should be taken with some water and not chewed or crushed tablets.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Clinic, Shiraz, Iran
Full name of responsible person
Mahtab Rostamihosseinkhani
Street address
Epilepsy department, Namazi hospital, Namazi Sq, Zand St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Younes Ghasemi
Street address
Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd
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Postal code
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Phone
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Fax
+98 71 3230 7594
Email
vcrdep@sums.ac.ir
Web page address
http://research2.sums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Mahtab Rostamihosseinkhani
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Title and more details about the data/document
All collected deidentified IPD are to be shared
When the data will become available and for how long
Starting 6 months after publication
To whom data/document is available
People working in academic institutions
Under which criteria data/document could be used
To help further research to improve the treatment of refractory temporal lobe epilepsy
From where data/document is obtainable
Mahtab Rostamihosseinkhani
mahtabrostami85@yahoo.com
What processes are involved for a request to access data/document
Send their request to the mentioned email address and within one working week, if there is no problem, the data will be sent to them.
Comments