

# 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 will 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)

###### Phone

+98 71 3820 6907

###### Email address

mahtabrostami85@yahoo.com

##### 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**

**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 dioxide). 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

**City**

Shiraz

**Province**

Fars

**Postal code**

7193613311

**Phone**

+98 71 3612 5840

**Email****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

**City**

Shiraz

**Province**

Fars

**Postal code**

71345-1978

**Phone**

+98 71 3235 7282

**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

**Street address**

Epilepsy Department, Namazi Hospital, Namazi Sq,

Zand St.  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7193613311  
**Phone**  
+98 71 3612 5840  
**Email**  
Mahtabrostami85@yahoo.com

## Person responsible for scientific 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  
**Street address**  
Epilepsy Department, Namazi Hospital, Namazi Sq,  
Zand St.  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7193613311  
**Phone**  
+98 71 3612 5840  
**Email**  
Mahtabrostami85@yahoo.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Mahtab Rostami Hosseinkhani  
**Position**  
Resident  
**Latest degree**  
Medical doctor

### Other areas of specialty/work

Neurology  
**Street address**  
Epilepsy Department, Namazi Hospital, Namazi Sq,  
Zand St.  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7193613311  
**Phone**  
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**Email**  
Mahtabrostami85@yahoo.com

## 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