

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Efficacy of adjunctive use of Verapamil with two doses 120 and 240 mg on control of seizure in patients with refractory temporal lobe epilepsy

#### Protocol summary

##### Summary

Goal: To decrease the seizure frequency and severity  
Inclusion criteria: Refractory temporal lobe epileptic patients that had not respond to 2 correctly selected anti epileptic drugs  
Exclusion criteria: Verapamil usage  
Contraindication  
Study population: Refractory temporal lobe epileptic patients  
Sample size: 20 patients  
Intervention: Verapamil prescription in one group as 120 mg per day and 240 mg per day in the second group  
Time-point and primary outcome: In the first 2 months evaluating seizure frequency and type then following 2 months evaluating same things while adding Verapamil tab to medication regime

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2012121711778N1**  
Registration date: **2013-03-02, 1391/12/12**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2013-03-02, 1391/12/12

##### Registrant information

##### Name

Seyed mohammad ali Razavizadegan Jahromi

##### Name of organization / entity

Shiraz University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71123054109

##### Email address

razavima@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2012-11-21, 1391/09/01

##### Expected recruitment end date

2012-11-30, 1391/09/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of adjunctive use of Verapamil with two doses 120 and 240 mg on control of seizure in patients with refractory temporal lobe epilepsy

##### Public title

Verapamil effect on refractory epilepsy treatment

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: - Male/female patients, aged 18 and above. - Diagnosis of epilepsy made on the basis of clinical and EEG findings. - Refractory epilepsy is defined as failure of two or more AEDs at maximal tolerated doses and 2 or more seizures per month. - There have been no more than 4 weeks between seizures over the 2 months prior to entry to the study. - Having stable medication regimen for 8 weeks prior to entry. - Patient is male or a non-pregnant female adequately protected from conception. - Informed consent by patients or their families/care givers. Exclusion criteria: - Patient has a progressive neurological condition. - Patient has a history of non-compliance for seizure diary completion or frequent clinic visits. - Patient is pregnant at the time of enrolment. - Patient has any serious medical illness or

major psychiatric disorder, history of pseudoseizure, or history of suicidal attempt in the past 5 years. - Patient has any contraindication for verapamil administration including: severe GI narrowing, heart failure, hypertrophic cardiomyopathy, cardiac conduction disturbances, hypotension, hepatic impairment, renal impairment, and known history of hypersensitivity to verapamil.

#### Age

From **18 years** old to **53 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **20**

#### Randomization (investigator's opinion)

N/A

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shiraz University of Medical Science

##### Street address

Central building of Shiraz University of Medical Science, Zand street, Shiraz

##### City

Shiraz

##### Postal code

7134814336

#### Approval date

2012-07-12, 1391/04/22

#### Ethics committee reference number

CT-P-91-3629

## Health conditions studied

### 1

#### Description of health condition studied

epilepsy

#### ICD-10 code

G40.2

## ICD-10 code description

Localization-related (focal)(partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures

## Primary outcomes

### 1

#### Description

seizure frequency

#### Timepoint

monthly

#### Method of measurement

questionnaire and check list

### 2

#### Description

seizure quality

#### Timepoint

monthly

#### Method of measurement

questionnaire and check list

## Secondary outcomes

### 1

#### Description

blood pressure

#### Timepoint

one week after starting Verapamil, one week after titrating Verapamil, and then monthly

#### Method of measurement

Digital blood pressure monitor

### 2

#### Description

pulse rate

#### Timepoint

one week after starting Verapamil, one week after titrating Verapamil, and then monthly

#### Method of measurement

counting manually

## Intervention groups

### 1

#### Description

Adding Verapamil tab as 120 mg daily to previous anti epileptic drugs in patients with refractory temporal lobe epilepsy for 2 months and then comparing the changes in seizure frequency and quality to previous same time.

#### Category

Treatment - Drugs

### 2

#### Description

Adding Verapamil tab as 240 mg daily to previous anti

epileptic drugs in patients with refractory temporal lobe epilepsy for 2 months and then comparing the changes in seizure frequency and quality to previous same time.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza Clinic, Shiraz University of Medical Science

##### Full name of responsible person

Dr seyed mohammad ali razavizadegan jahromi

##### Street address

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Science

##### Full name of responsible person

Deputy director of inquiry of Shiraz University of Medical Science

##### Street address

Central building of Shiraz University of Medical Science, Zand street, Shiraz

##### City

Shiraz

##### 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 Science

##### Proportion provided by this source

100

##### Public or private sector

*empty*

##### Domestic or foreign origin

*empty*

##### Category of foreign source of funding

*empty*

##### Country of origin

##### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Science

##### Full name of responsible person

Seyed mohammad ali razavizadegan jahromi

##### Position

Neurology resident

##### Other areas of specialty/work

##### Street address

The forth section, Second floor, Apartment in the end, 9/5, Alley 9, South Safir Street, Shiraz

##### City

Shiraz

##### Postal code

7178858618

##### Phone

+98 71 1835 7279

##### Fax

##### Email

alirazavi1357@gmail.com razavima@sums.ac.ir

##### Web page address

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Science

##### Full name of responsible person

Seyed mohammad ali razavizadegan jahromi

##### Position

Neurology resident

##### Other areas of specialty/work

##### Street address

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alirazavi1357@gmail.com razavima@sums.ac.ir

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## Person responsible for updating data

#### Contact

##### Name of organization / entity

Shiraz University of Medical Science

##### Full name of responsible person

Seyed mohammad ali razavizadegan jahromi

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*