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 fallowing 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 psudoseizure, 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

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City

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Postal code

Phone

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Fax

Email

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

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Science

Full name of responsible person

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Web page address

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