

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparing efficacy and tolerability of lamotrigine and levetiracetam in elderly patient with diagnosed epilepsy

Protocol summary

Summary

Choosing the right drug with the least side effects and highest effectiveness for the control of epilepsy in the elderly population is important. This study compared the lamotrigine efficacy with levetiracetam in the management of epilepsy in the elderly. The patients with age more than 60y and one year history of epilepsy were enrolled in this study. The study was double-blind randomized clinical trial. Patients were divided randomly into two groups. Group I and Group II treated with treated with lamotrigine were Lvtyrastam. The follow up of patients were done in 2, 4, 8, 12 and 20 week after completion of treatment to assessment of number of epilepsy attack, abnormality of lab test and drug complication. The patients were exclude due to lack of follow-up, severe medical complications and death.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013021211560N3**

Registration date: **2013-05-18, 1392/02/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-05-18, 1392/02/28

Registrant information

Name

Tayeb Ramim

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Deputy of Research, Tehran University of Medical
Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing efficacy and tolerability of lamotrigine and
levetiracetam in elderly patient with diagnosed epilepsy

Public title

Epilepsy management in elderly

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : age>60 years old; one year diagnosis;
two or more attack in the last year; one and more attack
in 6 months ago; life expectancy more one year;
unprovoked or generalized epilepsy; no history of
lamotrigine and levetiracetam sensitivity and no history
of mental disorder. Exclusion criteria: no tolerability to
drug reaction; severe complication; lost to follow up;
drug and alcohol abuse; low level of consciousness after
drug use due to underlying disease and death.

Age

From **65 years** old to **100 years** old

Gender

Both

Phase

2-3

Groups that have been masked*No information***Sample size**Target sample size: **95****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran University of Medical Science

Street address

Hemat gateway, Central division of Tehran University of Medical Sciences

City

Tehran

Postal code**Approval date**

2011-09-23, 1390/07/01

Ethics committee reference number

827

Health conditions studied**1****Description of health condition studied**

Elderly epilepsy

ICD-10 code

G40

ICD-10 code description

Epilepsy

Primary outcomes**1****Description**

Epilepsy management

Timepoint

Four weeks after drug use

Method of measurement

Interview

Secondary outcomes

empty

Intervention groups**1****Description**

Lamotrigine was start in 25mg/day and continue to 200mg/day

Category

Treatment - Drugs

2**Description**

Levetiracetam was start in 250mg/day and continue to 1000mg/day

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sina Hospital

Full name of responsible person

Dr. Pardis Etemadi

Street address

Sina Hospital, Imam Khomeini St, Hasan Abad Sq

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Deputy of Research, Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

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Central building of Tehran University of Medical sciences, Ghods st., Keshavarz blv.

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Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Deputy of Research, Tehran University of Medical Sciences

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**

Sina Hospital, Tehran University of Medical Sciences

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MD, Neurology assistant

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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*