

# A Multicentre, Double-Blind, Randomised, Parallel-Group, Positive-Controlled Trial Comparing the Efficacy and Safety of Levetiracetam With That of Carbamazepine, Used as Monotherapy for up to a Maximum of 121 Weeks in Subjects (≥16 Years) Newly or Recently Diagnosed as Suffering From Epilepsy and Experiencing Partial or Generalised Tonic-Clonic Seizures

**Short title: Levetiracetam for the Treatment of Newly Diagnosed Epilepsy in Adolescents and Adults**

## Background

- The term 'epilepsy' is derived from the Greek word 'epilamvanein', which means 'to seize' or 'to attack'. It involves episodes of excessive electrical activity in the brain that can manifest in many different ways, with the episodes being called seizures.<sup>1</sup>
- Some seizures manifest as only an unusual feeling or sensation, while others may involve temporary loss of awareness of surroundings. Other seizure types result in the patient falling to the ground with jerky body movements, tongue biting, urination, or loss of bowel control.<sup>2</sup>
- Partial seizures involve only a limited region of the brain, whereas generalized seizures involve the whole brain.<sup>1</sup>

## Purpose of the study

- To determine if treatment using a single therapy (monotherapy) with levetiracetam (Keppra® tablets) in comparison with carbamazepine was at least as effective in achieving 6 months of seizure freedom in patients with newly or recently detected epilepsy, and suffering from partial or generalised seizures.
- To determine if levetiracetam monotherapy is well tolerated by these patients.

## Study participants

- The study included 579 male and female patients, aged 16 years and older, with newly or recently diagnosed epilepsy and having experienced at least two unprovoked partial or generalised seizures separated by at least 48 hours during the past year, with at least one unprovoked seizure in the past 3 months.

## Study design and research methodology

- The study was conducted in 85 centres across Belgium, Czech Republic, Finland, France, Germany, Hungary, Italy, Netherlands, Poland, South Africa, Spain, Sweden and the United Kingdom between June 2002 and July 2005. Patients participated in the study for a maximum of 121 weeks.
- The patients were given different doses of either levetiracetam orally twice a day or carbamazepine orally twice a day. After 29 weeks of total medicine exposure, 6-month seizure freedom was measured. Patients achieving this 6-month seizure freedom continued on treatment for a further 6-month maintenance.
- Side effects were also studied.

## Key findings

- Patients were seizure-free for 6 months to a similar degree in both treatment groups.
- Overall, similar percentage of patients in both treatment groups experienced at least one treatment-related side effect.
- Most of the side effects were mild to moderate in intensity.
- The most common side effects reported in at least 3% of the patients within each treatment group were headache, fatigue, somnolence (drowsiness), dizziness, nasopharyngitis (viral infection of the upper respiratory system), influenza (flu), diarrhoea, nausea, vertigo (sensation of whirling motion), weight gain, back pain, depression, insomnia and rash.
- No follow-up trials are foreseen for this study.

## Peer-reviewed publication

[Brodie MJ, Perucca E, Ryvlin P, et al. Comparison of levetiracetam and controlled-release carbamazepine in newly diagnosed epilepsy. \*Neurology\*. 2007;68\(6\):402-408.](#)

## References:

1. Singh M, Kaur S. Epilepsy detection using EEG: An overview. *Int J Inf Technol Knowl Manag*. 2012; 6:3-5.
2. Kellinghaus C, Luders H. Classification of seizures. In: Wyllie E, eds. *Wyllie's Treatment of Epilepsy Principles and Practice*. 5th ed. Philadelphia: Wolters Kluwer/Lippincott Williams & Wilkins; 2011:134-143.

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