

A Multicentre, Double-Blind, Randomised, Placebo-Controlled, Parallel-Group Trial to Investigate the Efficacy and Safety of Lacosamide as Adjunctive Therapy in Subjects With Partial Seizures With or Without Secondary Generalisation

Short title: Lacosamide for the Treatment of Epileptic Partial Seizures in Adolescents (16 years and older) 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.¹
- 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.²
- Partial seizures involve only a limited region of the brain, whereas generalized seizures involve the whole brain.¹

Purpose of the study

- To determine if add-on treatment with lacosamide (Vimpat[®]), in combination with 1 to 3 other medicines used to treat seizures, decreases seizures in patients with partial seizures who had failed to improve with other treatments.
- To determine if lacosamide is well tolerated by these patients.

Study participants

- The study included 485 female and male adolescent and adult patients aged 16-70 years with partial seizures not properly controlled for at least the last 2 years despite prior therapy with at least 2 other medicines (medicines taken simultaneously or consecutively).
- Patients were taking a maximum of 3 medicines, other than lacosamide, to treat partial seizures. They kept taking those medicines during the conduct of the study.

Study design and research methodology

- The study was conducted in 75 centres across Australia, Croatia, Czech Republic, Finland, France, Germany, Hungary, Lithuania, Poland, Russia, Spain, Sweden, and the UK between June 2004 and January 2006. Patients participated in the study for a maximum of 6.5 months.
- The study participants were equally divided into 3 groups and were randomly given either of the doses of lacosamide tablets or placebo tablets 2 times a day.
- After 16 weeks of total medicine exposure, including 12 weeks at the medicine target dose, the patients were followed to document the number of seizures they experienced during the study.
- The percentage of patients in whom the number of seizures decreased by half and the percentage of patients who had no seizures were calculated.
- Side effects were also studied.

Key findings

- More patients treated with lacosamide compared to placebo:
 - Showed decreased number of seizures
 - Had decreased the number of seizures by at least half
 - Achieved seizure freedom (particularly with the higher dose of lacosamide).
- Most of the side effects were mild to moderate in intensity. More patients treated with lacosamide showed side effects compared with those treated with placebo.
 - The most common side effects reported in at least 5% of patients treated with lacosamide were dizziness, headache, double vision, nausea, vertigo (sensation of whirling motion), fatigue, nasopharyngitis (viral infection of the upper respiratory system), abnormal coordination, and vomiting.
- Patients who completed the study and who were willing to continue treatment with lacosamide were included in a follow-up study conducted over 5,5 years to assess the long-term safety and efficacy of lacosamide [NCT00515619].

Peer-reviewed publication

[Halasz P, Kalviainen R, Mazurkiewicz-Beldzinska M, et al. Adjunctive lacosamide for partial-onset seizures: Efficacy and safety results from a randomized controlled trial. *Epilepsia*. 2009;50:443-453.](#)

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.
3. Assess Safety and Efficacy of Lacosamide in Patients With Partial Seizures [NCT00515619]. Clinicaltrials.gov Web Site. Available at: <http://www.clinicaltrials.gov/ct2/show/NCT00515619?term=NCT00515619&rank=1>. Accessed on December 9th, 2014.

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