

# 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**

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| <b>Background</b>                                   | <ul style="list-style-type: none"><li>• 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></li><li>• 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></li><li>• Partial seizures involve only a limited region of the brain, whereas generalized seizures involve the whole brain.<sup>1</sup></li></ul>  |
| <b>Purpose of the study</b>                         | <ul style="list-style-type: none"><li>• To determine if add-on treatment with lacosamide (Vimpat<sup>®</sup>), in combination with 1 to 3 other medicines used to treat seizures, improves seizure control in patients with partial seizures who had failed to improve with other treatments.</li><li>• To determine if lacosamide is well tolerated by these patients.</li></ul>  |
| <b>Study participants</b>                           | <ul style="list-style-type: none"><li>• The study included 405 male and female adolescent and adult patients aged 16-71 years with partial seizures whose symptoms were not properly controlled despite treatment with at least 2 other medicines for at least 2 years (medicines taken simultaneously or consecutively).</li><li>• Patients were taking a maximum of 3 medicines other than lacosamide to treat partial seizures.</li><li>• They continued taking those medicines for the duration of the study.</li></ul>  |
| <b>Study design and research methodology</b>        | <ul style="list-style-type: none"><li>• The study was conducted in 72 centres in the United States between March 2004 and August 2006. Patients participated in the study for a maximum of 29 weeks.</li><li>• Study participants were divided into 3 groups and randomly assigned to receive either of 2 doses of lacosamide or placebo. They were asked to take the medicine 2 times daily.</li><li>• After 18 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.</li><li>• The percentage of patients in whom the number of seizures decreased by half and the percentage of patients who had no seizures were calculated.</li><li>• Side effects were also studied.</li></ul>  |
| <b>Key findings</b>                                 | <ul style="list-style-type: none"><li>• More patients treated with lacosamide compared with placebo:<ul style="list-style-type: none"><li>○ Showed decreased number of seizures</li><li>○ Had decreased the number of seizures by at least half</li></ul></li><li>• In addition, several patients treated with lacosamide were seizure free, whereas no patients in the placebo group were seizure free.</li><li>• 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.</li><li>• The most common side effects (seen in at least 10% of patients treated with lacosamide) were dizziness, nausea, double or blurred vision, headache, vomiting, tremor (unintentional muscle movement), abnormal coordination, somnolence (drowsiness), and nystagmus (uncontrollable eye movements).</li><li>• Patients who completed the study and who were willing to continue treatment with lacosamide were included in a follow-up study conducted over 5 years to assess the long-term safety and efficacy of lacosamide [NCT00522275].</li></ul> |
| <b>Peer-reviewed publication</b>                    | <a href="#">Chung S, Sperling MR, Biton V, et al. Lacosamide as adjunctive therapy for partial-onset seizures: a randomized controlled trial. <i>Epilepsia</i>. 2010;51:958-967.</a>   |
| <b>Peer-reviewed publication of follow-up trial</b> | <a href="#">Husain A, Chung S, Faught E, Isojarvi J, McShea C, Doty P. Long-term safety and efficacy in patients with uncontrolled partial-onset seizures treated with adjunctive lacosamide: results from a Phase III open-label extension trial. <i>Epilepsia</i>. 2012;53:521-528.</a>  |

## 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*. 5<sup>th</sup> ed. Philadelphia: Wolters Kluwer/Lippincott Williams & Wilkins; 2011:134-143.

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