

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 in Adults for the Treatment of Epileptic Partial Seizures

Background	<ul style="list-style-type: none">• The term 'epilepsy' is derived from the Greek word 'epilambanein', which means 'to seize' or 'to attack'. It involves episodes of excessive electrical activity in the brain that can manifest in many different ways, called seizures.¹• Some seizures manifest as only an unusual feeling or sensation, while others may involve loss of awareness of surroundings. There are also some other seizures that involve falling to the ground with jerky body movements, tongue biting, urination, and loss of bowel control.²• Partial onset seizures, also called focal seizures, involve only a limited region of the brain, whereas other types involve the whole brain from the beginning of the seizure.¹
Purpose of the study	<ul style="list-style-type: none">• To check whether lacosamide (Vimpat®) used in combination with 1 or 2 other anti-epileptic drugs (AEDs), improves seizure control in patients with focal seizures who had failed to improve with other treatments.• To evaluate if lacosamide has an acceptable safety profile in these patients.
Study participants	<ul style="list-style-type: none">• The study included 418 female and male adult patients aged 18 to 68 years with focal seizures not properly controlled for at least the last 2 years despite prior therapy with at least 2 other AEDs.• Patients were taking AEDs other than lacosamide to treat focal seizures: 84% of patients were taking 2 other AEDs and 16% of patients were taking 1 other AED. They kept taking those AEDs during the conduct of the study.
Study design and research methodology	<ul style="list-style-type: none">• The study was conducted in 68 centres in Germany, Hungary, Lithuania, Poland, Sweden, Switzerland, the UK, and the USA between February 2002 and May 2004. Participation of a patient in this study was not longer than 29 weeks.• The patients were equally divided into 4 groups and were given either different doses of lacosamide or placebo (dummy medicine) orally 2 times a day along with 1 or 2 other AEDs to treat focal seizures.• After 18 weeks of total lacosamide exposure including 12 weeks at the lacosamide target dose, the researchers checked the patients for decrease in the number of seizures. They calculated the percentage of patients in whom the number of seizures decreased by half and of patients who had no seizures.• Side effects were also studied.
Key findings	<ul style="list-style-type: none">• More patients receiving lacosamide at all doses showed decrease in the number of seizures by half compared with patients receiving placebo.<ul style="list-style-type: none">○ Patients receiving higher doses of lacosamide showed better improvements in control of seizures compared with patients receiving lower dose.• Seven patients in the lacosamide groups were seizure free, whereas no patients were seizure free in the placebo group.• Side effects were more common in the lacosamide groups (particularly with highest dose) compared with the placebo group. Most of the side effects were mild to moderate in intensity.<ul style="list-style-type: none">○ The most common side effects reported in at least 10% of patients in either of the treatment groups were dizziness, headache, nausea, fatigue, ataxia, abnormal vision, vomiting, diplopia (double vision), somnolence (drowsiness), infections of the respiratory system, unspecified accidents, and nystagmus (uncontrollable eye movements).• Patients who completed this study were followed for an additional period of up to 8 years to further assess the effect of lacosamide on symptom improvement and its long-term safety.
Peer-reviewed	<p>Ben-Menachem E, Biton V, Jatuzis D, Abou-Khalil B, Doty P, Rudd GD. Efficacy and safety of oral lacosamide as adjunctive therapy in adults with partial-onset seizures. <i>Epilepsia</i>. 2007;48:1308-1317.</p>

Reference:

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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