

Open-Label, Single-Arm, Multicentre, Pharmacokinetic, Safety and Tolerability Study of Levetiracetam Intravenous Infusion In Children (1 Month to < 4 Years Old) With Epilepsy

Short title: Levetiracetam for Treatment of Epilepsy in Children (1 Month Old to < 4 Years Old)

Background	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• To determine if add-on treatment or monotherapy (i.e., treatment using a single therapy) with levetiracetam provided intravenously (Keppra[®] injection) had an acceptable safety and tolerability profile in children with any type of epilepsy (except one type of epilepsy called 'status epilepticus') who are unable to take oral medicine.• To study the effect of levetiracetam, provided intravenously, in the body.
Study participants	<ul style="list-style-type: none">• The study included 19 male and female children, aged 1 month to < 4 years, with weight of at least 3 kg, with any type of epilepsy (except one type of epilepsy called 'status epilepticus') requiring short-term in-hospital levetiracetam intravenous treatment.
Study design and research methodology	<ul style="list-style-type: none">• The study was conducted in 24 centres across Belgium, France, Germany, Mexico, Turkey and the United States between May 2008 and March 2010. Patients participated in the study for a maximum of 25 days.• The patients were given either low or high dose of levetiracetam, intravenously, twice a day.• After 4 days of total levetiracetam exposure, the patients were checked for blood plasma concentrations of levetiracetam.• Side effects were also studied.
Key findings	<ul style="list-style-type: none">• The plasma concentrations of levetiracetam were found to be in the expected range.• More than half of the patients reported treatment-related side effects during the study period.• Most of the side effects were mild to moderate in intensity.• The most common side effects reported in at least 11% of the patients were pyrexia (fever), pneumonia (inflammatory condition of the lung), bradycardia (slow heart rate), hypotension (low blood pressure), and metabolic acidosis (the condition when the body produces too much acid or when the kidneys do not remove enough acid from the body).• The proportion of patients showing side effects was higher in the high-dose levetiracetam group than in the low-dose group.<ul style="list-style-type: none">○ Bradycardia and pneumonia were the most frequently reported side effects in patients receiving low dose of levetiracetam, and pyrexia was the most frequently reported side effect in patients receiving high dose of levetiracetam.• No follow-up trials are foreseen for this study.
Peer-reviewed publication	<p>Weinstock A, Ruiz M, Gerard D, et al. Prospective open-label, single-arm, multicenter, safety, tolerability, and pharmacokinetic studies of intravenous levetiracetam in children with epilepsy. <i>J Child Neurol.</i> 2013;28(11):1423-1429.</p>

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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