A Multicentre, Randomised, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Ranging Study to Assess the Efficacy, Safety, and Tolerability of Escalating Transdermal Doses of Rotigotine in Subjects With Early-Stage Parkinson's Disease

Short title: Rotigotine in Adults for the Treatment of Early Parkinson's Disease

Background	• Parkinson's disease is a progressive illness, which means symptoms appear gradually and slowly get worse. Everyone with Parkinson's disease has different symptoms, but the most common symptoms are uncontrollable shaking (tremor), stiffened muscles (muscle rigidity), and slowness of movement. All of these symptoms are related to movement and are called motor symptoms. Many people with Parkinson's disease may also have other problems not related to movement, such as pain, fear and worry (anxiety), and feeling low (depression). These are called non-motor symptoms.[1]
Purpose of the study	• To see if rotigotine transdermal patch (Neupro®) improves symptoms in patients with early Parkinson's disease. • To assess the safety and tolerability profiles of rotigotine transdermal patch in patients with early Parkinson's disease.
Study participants	• The study included 242 female and male patients aged more than 30 years with idiopathic (ie, of unknown cause) early Parkinson's disease who had not received prior treatment with medicines that affect the action of the chemical messenger dopamine.
Study design and research methodology	• The data presented are for patients who participated in the study conducted at 36 Parkinson Study Group (PSG) sites in USA and Canada between Nov 1999 and Aug 2000. Participation of a patient in this study was approximately 18 weeks. • Study participants were randomly equally divided into 5 groups and were given either different doses of rotigotine or placebo (dummy medicine) via transdermal patch daily. • During every visit and after 11 weeks, the patients were checked for betterment in ability to perform normal daily activities and movement control. • The patients were also checked for any side effects throughout the study until 14 weeks.

Key findings	• More patients receiving rotigotine compared with placebo had improvements in movement control.
	  ○ Increase in the dose of rotigotine resulted in an increased improvement in symptoms.
	• During the 14-week study period, 91% of all patients showed at least 1 side effect. Most side effects were mild to moderate in intensity.
	  ○ The most common side effects reported in at least 5% of patients in either of the treatment groups were nausea, skin reactions at the site of application, dizziness, somnolence (drowsiness), insomnia (difficulty falling asleep or staying asleep), headache, vomiting, fatigue, sweating, diarrhoea, anxiety, oedema and loss of hunger.
	• Incidence of study withdrawals due to side effects was similar between placebo and rotigotine groups. Eight patients treated with rotigotine withdrew due to application site reactions.
	• No follow-up trials are foreseen for this study.

Peer-reviewed publication	The Parkinson Study Group. A controlled trial of rotigotine monotherapy in early Parkinson's disease. *Arch Neurol*. 2003;60(12):1721-1728.

Reference:

1 European Parkinson's Disease Association. http://www.epda.eu.com/en/pd-info/about-parkinsons/. Accessed 01 Jun 2016.

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