A Multicentre, Multinational, Phase 3, Randomised, Double-Blind, Parallel Group, Placebo-Controlled Trial of the Efficacy and Safety of Rotigotine Patch (2 Target Doses) in Subjects With Advanced-Stage, Idiopathic Parkinson's Disease who are Not Well Controlled on Levodopa (Part 1).

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

Background[1]	• 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 adjunctive therapy of rotigotine (Neupro®) transdermal patch with levodopa improves symptoms in patients with idiopathic (i.e., of unknown cause) advanced Parkinson's disease who do not get better with levodopa. • To assess the safety and tolerability profile of rotigotine transdermal patch in patients with idiopathic advanced Parkinson's disease.
Study participants	• The study included 351 female and male patients aged 30 years or more with advanced Parkinson's disease. These patients were not adequately controlled with their current levodopa dose thus facing time periods with loss of treatment effect called 'off-time' being ≥2.5 hours per day.
Study design and research methodology	• The study was conducted at 54 sites in the USA and Canada between December 2001 and April 2004. Participation of a patient in this study was approximately 34 weeks. • The patients were equally divided into 3 groups and were randomly given either of the 2 doses of rotigotine or placebo via a transdermal patch every 24 hours • After 24 weeks, the patients were checked for a decrease in their daily loss of treatment efficacy time periods and the number of responders defined as patients showing at least 30% decrease in their off-time. They were also checked for decrease in the amount of time they spent without troublesome sudden uncontrolled body movements. • Side effects were also studied.

Key findings	• More patients treated with rotigotine compared with placebo showed:
	  ○ Decrease in their daily loss of treatment efficacy time periods.
	  ○ Increase in the amount of time they spent without troublesome sudden uncontrolled body movements.
	  ○ Improvement in the symptoms of advanced Parkinson's disease.
	• There were more responders in rotigotine group compared with placebo group.
	• Most side effects in both groups were mild to moderate in intensity.
	• The most common side effects seen in at least 5% of patients treated with rotigotine were skin reactions at the site of patch application, somnolence (drowsiness), nausea and vomiting, dizziness, sudden uncontrolled body movements (dyskinesia), headache, peripheral oedema (swelling), insomnia (difficulty falling asleep or staying asleep), constipation, and perception disturbances.
	• Patients who completed this study were followed for an additional period of up to 6 years to further assess the long-term safety of rotigotine.[2]

Peer-reviewed publication

LeWitt PA, Lyons KE, Pahwa R. Advanced Parkinson disease treated with rotigotine transdermal system: PREFER Study. *Neurology*. 2007;68:1262-1267.

References:

1. European Parkinson's Disease Association. http://www.epda.eu.com/en/pd-info/about-parkinsons/. Accessed 01 Jun 2016.
2. A multi-center, multinational, phase III, randomized, double-blind, parallel group, placebo controlled trial of the efficacy and safety of rotigotine CDS patch (2 target doses) in subjects with advanced stage, idiopathic Parkinson's disease who are not well controlled on levodopa (Part I) and open-label extension to assess the safety of long-term treatment of rotigotine CDS (Part II). [NCT00594386]. Clinical Study Synopsis. 2010.

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