

# A Multicentre, Multinational, Phase III, Randomised, Double-Blind, Placebo-Controlled Trial of the Efficacy and Safety of the Rotigotine Patch in Subjects With Early-Stage, Idiopathic Parkinson's Disease

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

<b>Background</b>	<ul style="list-style-type: none"><li>• 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.<sup>1</sup></li></ul>
<b>Purpose of the study</b>	<ul style="list-style-type: none"><li>• To see if the rotigotine transdermal patch (Neupro®) improves symptoms of early stage Parkinson's disease.</li><li>• To assess the safety and tolerability profile of rotigotine transdermal patch in patients with early Parkinson's disease.</li></ul>
<b>Study participants</b>	<ul style="list-style-type: none"><li>• The study included 277 female and male patients aged at least 30 years with idiopathic (ie, of unknown cause) early Parkinson's disease.</li></ul>
<b>Study design and research methodology</b>	<ul style="list-style-type: none"><li>• The study was conducted at 50 sites in the USA and Canada between November 2001 and April 2003. Participation of a patient in this study was approximately 35 weeks.</li><li>• Study participants were divided into 2 groups and were randomly given either rotigotine or placebo (dummy medicine) applied as transdermal patch daily.</li><li>• After 6 months, the patients were checked to see if they were better able to do normal daily activities and had less movement-related problems. Patients were defined as 'responders' when at least 20% of their symptoms improved.</li><li>• The patients were also checked for any side effects throughout the study.</li></ul>
<b>Key findings</b>	<ul style="list-style-type: none"><li>• More patients in the rotigotine group compared with placebo group had an improvement in movement control. Improvement in symptoms was seen during the initial 3-week study period, which was maintained for the next 6 months.</li><li>• There were more responders in the rotigotine group compared with placebo group.</li><li>• Side effects were similar between rotigotine and placebo groups.<ul style="list-style-type: none"><li>○ The most common side effects seen in at least 5% of patients treated with rotigotine were skin reactions at the site of application, nausea, somnolence (drowsiness), dizziness, headache, vomiting, insomnia (difficulty falling asleep or staying asleep), unspecified accidents, fatigue (tiredness), indigestion, tremor, constipation, diarrhoea, arthralgia (joint pain), back pain, and coughing.</li></ul></li><li>• Most of the side effects were mild to moderate in intensity.</li><li>• 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.<sup>2</sup></li></ul>
<b>Peer-reviewed publication</b>	Watts RL, Jankovic J, Waters C, Rajput A, Boroojerdi B, Rao J. Randomized, blind, controlled trial of transdermal rotigotine in early Parkinson disease. <i>Neurology</i> . 2007;68:272-276.
<b>Peer-reviewed publication of follow-up trial</b>	<u>Elmer LW, Surmann E, Boroojerdi B, Jankovic J. Long-term safety and tolerability of rotigotine transdermal system in patients with early-stage idiopathic Parkinson's disease: a prospective, open-label extension study. <i>Parkinsonism Relat Disord</i>. 2012;18(5):488-493.</u>

### References:

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

2. A multi-center, multinational, phase III, randomized, double-blind, placebo controlled trial, of the efficacy and safety of the rotigotine CDS patch in subjects with early stage, idiopathic Parkinson's disease (Part I), and an open-label extension to assess the safety of long-term treatment of rotigotine CDS (Part II) [NCT00594165]. Clinical Study Synopsis. 2010.

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