

A Multicentre, Multinational, Phase III, Randomised, Double-Blind, Double-Dummy, 3-Arm Parallel Group, Placebo- and Ropinirole-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

Background¹

- 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 find out if rotigotine transdermal patch (Neupro[®]) is helpful in patients with early Parkinson's disease compared with placebo (dummy medicine) and ropinirole, which is another medicine for the treatment of Parkinson's disease that affects the action of the chemical messenger dopamine.
- To assess the safety and tolerability profile of rotigotine transdermal patch in patients with early Parkinson's disease.

Study participants

- The study included 561 female and male patients aged at least 30 years with idiopathic (ie, of unknown cause) early Parkinson's disease.

Study design and research methodology

- The study was conducted at approximately 80 sites globally, including UK, Germany and Israel. Participation of a patient in this study was not longer than 45 weeks.
- Study patients were randomly divided into 3 groups:
 - The first group received rotigotine transdermal patch and placebo capsule 3 times a day orally.
 - The second group received ropinirole encapsulated tablet 3 times a day orally and placebo applied as a skin patch.
 - The third group received placebo as a capsule (3 times a day orally) and as a skin patch.
- After 41 weeks, the patients were checked to see if they were better able to do normal daily activities, had less movement-related problems, and had overall improvement in symptoms. Patients were defined as 'responders', when at least 20% of their symptoms were improved.
- Side effects were also studied.

Key findings

- More patients who got either rotigotine or ropinirole compared with placebo had
 - Improvement in symptoms of Parkinson's disease.
 - Improvement in movement control.
- There were more responders in the rotigotine and ropinirole groups than in the placebo group.
- The most common side effects seen in at least 5% of patients in either of the treatment groups were skin reactions at the site of application, dizziness, headache, nausea, vomiting, abdominal pain, constipation, indigestion, diarrhoea, joint pains, back pain, somnolence (drowsiness), and insomnia (difficulty falling asleep or staying asleep).
- Side effects were similar between the 2 active treatment groups (rotigotine and ropinirole) with the exception of skin reactions at the site of patch application which was more common in the rotigotine group.
- Most side effects were mild to moderate in intensity.
- 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

Giladi N, Boroojerdi B, Korczyn AD, Burn DJ, Clarke CE, Schapira AH. Rotigotine transdermal patch in early Parkinson's disease: a randomized, double-blind, controlled study versus placebo and ropinirole. *Mov Disord.* 2007;22:2398-2404.

References:

1. European Parkinson's Disease Association. <http://www.epda.eu.com/en/pd-info/about-parkinsons/>. Accessed 01 Jun 2016.
2. A multi-centre, multinational, phase III, randomised, double blind, double-dummy, 3-arm parallel group, placebo- and ropinirole-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) [NCT00599196]. Clinical Study Synopsis. 2010.

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