A Multicentre, Randomised, Double-Blind, Placebo-Controlled, Four-Arm Parallel-Group Trial to Investigate the Efficacy and Safety of Three Different Transdermal Doses of Rotigotine in Subjects With Idiopathic Restless Legs Syndrome

Short title: Rotigotine for the Treatment of Restless Legs Syndrome in Adults

Background[1]	• Restless legs syndrome is a disorder of the nervous system. The main symptoms include an unpleasant feeling in the legs and uncontrollable urge to move the legs. Most of the patients are facing difficulty in falling asleep and staying asleep.
Purpose of the study	• To determine if treatment with rotigotine (Neupro®) transdermal patch for 24 hours can be helpful in patients with idiopathic (i.e., of unknown cause) restless legs syndrome, both during the day and at night. • To determine if rotigotine is well tolerated by these patients.
Study participants	• The study included 458 adult female and male patients aged 18 to 75 years with idiopathic restless legs syndrome. • These patients either had not received treatment for restless legs syndrome previously or had shown improvement of symptoms with dopaminergic medicines.
Study design and research methodology	• The study was conducted in 49 centres across Austria, Finland, Germany, Italy, Netherlands, Spain, Sweden and the UK between May 2005 and August 2006. Patients participated in the study for a maximum of 8 months. • The study participants were randomly equally divided into 4 groups and were given either different doses of rotigotine or placebo via a transdermal patch every 24 hours. • After 6 months, the patients were followed to see whether their symptoms of restless legs syndrome had improved and how they felt overall. • Side effects were also studied.
Key findings	• More patients treated with rotigotine transdermal patches showed improvement in symptoms compared with placebo: o Patients in the rotigotine groups had less severe symptoms of restless legs syndrome and generally felt better compared with patients in the placebo group both during the day and at night. • Among the rotigotine groups, the improvement in symptoms was more with higher doses compared with lower doses. • Side effects were seen in more patients treated with rotigotine compared with placebo. • The most common side effects reported in at least 5% of patients in any of the groups were skin reactions at the site of application of the patch, nausea, headache, fatigue, dry mouth, insomnia (difficulty falling asleep or staying asleep), hyperhidrosis (over-sweating), dizziness, and vertigo (sensation of whirling motion). • Most of the side effects were mild to moderate. • Patients who completed this study were followed for an additional period of up to 1 year to further assess the long-term safety of rotigotine [NCT00498108].[2]
Peer-reviewed publication	Trenkwalder C, Benes H, Poewe W, et al. Efficacy of rotigotine for treatment of moderate-to-severe restless legs syndrome: a randomised, double-blind, placebo-controlled trial. *Lancet Neurol.* 2008;7:595-604.

References:

1. Silber MH. Sleep-related movement disorders. Continuum (Minneap Minn). 2013;19(1 Sleep Disorders):170-184.
2. An open-label extension trial to investigate the safety and tolerability of long-term treatment with transdermal rotigotine in subjects with idiopathic Restless Legs Syndrome (RLS) [NCT00498108]. http://www.clinicaltrials.gov/ct2/show/NCT00498108?term=NCT00498108&rank=1 .

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