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Keywords (up to 5)	
Unlabelled use of products disclosure	Rotigotine transdermal system is licensed by the FDA for the treatment of early stage idiopathic Parkinson's disease, but not for the treatment of advanced stage idiopathic Parkinson's disease or treatment of the signs and symptoms of restless legs syndrome. Rotigotine transdermal system is not currently on the US market.
Practice gap statement	Rotigotine transdermal system is available in Europe for the treatment of early- and late-stage idiopathic PD and moderate to severe RLS, but is not currently available in the USA (although it is licensed by the FDA for the treatment of early stage PD). This study aims to assess the level of medical need for rotigotine and the impact of rotigotine in these patients; at the same time, this study will facilitate access to rotigotine for those patients who have a documented medical need for this treatment option and may benefit from its use, but who are unable to obtain rotigotine while it remains unavailable commercially in the USA.
Please explain the scientific relevance of this abstract:	

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Subject demographics and clinical characteristics in rotigotine transdermal system named patient program

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Objective: Overview study design and preliminary characteristics of subjects eligible for enrollment in an ongoing named patient program of rotigotine transdermal system (Study SP953 [NCT01095484]).

Background: Rotigotine is a unique dopamine agonist with D1-D5 receptor activity and select adrenergic and serotonergic sites, developed for continuous transdermal drug delivery over 24 hours for treatment of Parkinson's disease (PD) and restless legs syndrome (RLS). Rotigotine is approved by the FDA for treatment of early stage idiopathic PD, but not advanced idiopathic PD or RLS; rotigotine is not currently on the US market. This study aims to allow qualified US patients with a documented medical necessity to receive rotigotine, until it returns to the US market.

Design/Methods: Subjects with a diagnosis of PD or RLS and a documented medical necessity for rotigotine treatment are eligible, regardless of previous rotigotine exposure. Subjects must have failed treatment with other dopamine agonists ('failure' defined as suboptimal symptom control or intolerable adverse events [AEs]). Subjects taking rotigotine at study entry continue at their same dose. Subjects previously discontinuing rotigotine, or rotigotine-naïve, receive starting doses of 1 (RLS), 2 (early PD), or 4 mg/24h (advanced PD), which may be titrated to maximum doses of 3, 6 and 8 mg/24h, respectively. Clinic visits are at maximum 3-month

intervals to assess AEs, concomitant medication, treatment compliance, and for study medication resupply.

Results: As of September 12, 2011, 337 subjects (58% male, average age: 66.2 years) eligible for enrollment had a primary diagnosis of RLS, early PD, or advanced PD (14%, 25%, and 59%, respectively). 64% were rotigotine-naïve; 36% had prior exposure to rotigotine, 94% were previously treated with another dopamine agonist (pramipexole [29%], ropinirole [44%], or both [21%]).

Conclusions: Evaluation of patient demographic data and prior dopamine agonist use suggests a current unmet need for rotigotine access in some patients.