Single-site, open-label, randomized, crossover study in healthy subjects to evaluate bioequivalence of rotigotine transdermal patches (2mg/24H) from 2 different manufacturing sites

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Interventional

Summary

ID

NL-OMON42064

Source
ToetsingOnline

Brief title
Rotigotine transdermal patch bioequivalence study

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson, Restless Legs Syndrome

Research involving
Human

Sponsors and support

Primary sponsor: UCB BIOSCIENCES GmbH
Source(s) of monetary or material Support: Farmaceutische industrie

Intervention

Keyword: Parkinson, Restless Legs Syndrome (RLS), transdermal patches

Outcome measures

Primary outcome

To investigate and compare the relative bioavailability (BA) and single-dose pharmacokinetics (PK) of rotigotine transdermal patches from 2 different manufacturing sites to establish BE.

Secondary outcome

To investigate the safety, tolerability, and adhesiveness of rotigotine transdermal patches from the 2 different manufacturing sites.

Study description

Background summary

The rotigotine transdermal patch is an approved drug in the European Union (called Neupro®) and in the USA for the treatment of the symptoms of Parkinson*s disease and Restless Legs Syndrome (RLS).

Parkinson's disease is a result of there being less of a chemical called dopamine in the brain. This lack of dopamine causes symptoms such as shaking, muscle stiffness, and slow movement. Rotigotine is a dopamine-receptor agonist which means that it acts on the same receptors in the brain as dopamine. In effect, it acts like a partial substitute for dopamine and this helps to ease Parkinson's disease symptoms. It may be used alone, or in combination with other medicines to treat Parkinson's disease.

Restless Legs Syndrome is characterized by an uncomfortable feeling in the legs, which gives the urge to move the legs to get relief. Administration of

rotigotine can help when these feelings are severe enough to cause distress.

Study objective

Currently, all rotigotine transdermal patches are manufactured at 1 manufacturing site. A second site has been built to manufacture the same patches. Before these patches may be used, it needs to be investigated if they are exactly the same as those manufactured at the current site. Therefore, this study will compare the patches from both manufacturing sites with regard to how quickly and to what extent rotigotine is absorbed and eliminated from the body (this is called pharmacokinetics). This pharmacokinetic comparison is called a bioequivalence study. Further, the safety, tolerability and adhesiveness of the 2 different patches will be compared.

Study design

The actual study will consist of 2 periods. In both periods the volunteer will stay in the clinical research center in Zuidlaren from Day -1 to Day 3 (being 4 days and 3 nights). The time interval between Day -1 of each period is at least 5 days.

Intervention

In this study you will receive 2 different treatments:

Treatment A:
1 rotigotine transdermal patch from the *new* manufacturing site containing 2 milligrams of rotigotine applied for 24 hours on the skin

Treatment B:
1 rotigotine transdermal patch from the *old* manufacturing site containing 2 milligrams of rotigotine applied for 24 hours on the skin

Study burden and risks

As the rotigotine patch is already prescribed and used, adverse effects have been reported following its use. The very commonly reported adverse effects are feeling sick, vomiting, tiredness, localized skin irritations under the patch (such as redness and itching), sleepiness, dizziness and headache. Another adverse effect can be an allergic reaction that may include swelling of the face, lip and tongue.

Procedures: pain, minor bleeding, bruising, possible infection

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

healthy male and female subjects
18-55 yrs, inclusive
BMI: 19.0-28.0 kg/m2, inclusive

Exclusion criteria

Suffering from hepatitis B, hepatitis C, cancer or HIV/AIDS. In case of participation in another drug study within 90 days before the start of this study or being a blood donor within 60 days from the start of the study. In case of donating more than 1.5 liters of blood in the 10 months prior the start of this study.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-01-2015
Enrollment:	50
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Neupro®
Generic name:	rotigotine
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	18-11-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	01-12-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek

(Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2014-003014-81-NL
CCMO	NL51383.056.14