A single-site, open-label study in healthy male subjects to compare rotigotine saliva and plasma concentrations in steady-state after multiple-dose application of rotigotine transdermal patch

Published: 29-08-2011
Last updated: 28-04-2024

Primary:To evaluate the feasibility of using unconjugated rotigotine saliva concentrations as a surrogate for unconjugated rotigotine plasma concentrations.Secondary :To evaluate the effect of time of food intake on rotigotine concentrations in...

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

Summary

ID

NL-OMON35531

Source
ToetsingOnline

Brief title
Rotigotine transdermal patch study

Condition

- Movement disorders (incl parkinsonism)

Synonym
Parkinson's Disease, restless legs

Research involving

Human

Sponsors and support

Primary sponsor: UCB Pharma
Source(s) of monetary or material Support: UCB Pharma

Intervention

Keyword: Parkinson's disease, Restless legs Syndrome (RLS), Rotigotine

Outcome measures

Primary outcome

Pharmacokinetics: plasma and saliva rotigotine concentrations, pharmacokinetic

parameters

Safety: adverse events, vital signs, ECG-parameters, laboratory parameters,

physical examination, skin evaluation, C-SSRS

Secondary outcome

Not applicable.

Study description

Background summary

In previous studies in healthy volunteers, this 2mg/24h patch is considered well tolerated. The use of higher doses of rotigotine in healthy subjects is limited by tolerability issues, eg, nausea and vomiting. With the dose used in this study no serious adverse effects are expected. However, the possibility that any adverse effects could occur cannot be entirely excluded.

Study objective

Primary:
To evaluate the feasibility of using unconjugated rotigotine saliva concentrations as a surrogate for unconjugated rotigotine plasma concentrations.

Secondary :

To evaluate the effect of time of food intake on rotigotine concentrations in saliva

Study design

Design:
an open-label, randomized, two-way crossover study in fourteen healthy male subjects each receiving a rotigotine transdermal patch, for twenty-four hours, over a treatment period of seven days; subjects will be randomized to breakfast sequence early-late or late-early on Days 6 and 7

Intervention

Study Medication
Active substance: rotigotine
Activity: nonergolinic dopamine D3/D2/D1 agonist
Indication: parkinsons disease, restless legs syndrome
Strength: 4.5 mg/10 cm2
Dosage form: transdermal patch

Treatments
a transdermal patch for 24 hours applied once daily on days 1-7, containing 4.5 mg rotigotine/10 cm2 (2mg/24h)

Study burden and risks

Not applicable.

Contacts

Public
UCB Pharma

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Scientific
UCB Pharma

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

male; 18 - 25 years; BMI 19.0 - 28.0 kg/m2; no smoking; white skin.

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/AIDS. In case of participation in another drug study within 3 months the screening for the study or being a blood donor within 3 months prior to the screening for 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
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-10-2011
Enrollment:	14
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	29-08-2011
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	12-09-2011
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	EUCTR2011-002201-29-NL
CCMO	NL37833.056.11