A single-center, open-label, randomized, 3-way crossover study to compare the rate and extent of Rivastigmine absorption from two different formulations of 7 day Rivastigmine transdermal systems (7-day RTS) with 24-hour Exelon® patches applied daily for 7 days in healthy male and female subjects.

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To compare the rate and extent of rivastigmine absorption from two different formulations of 7-day rivastigmine transdermal systems (7-day RTS) with 24-hour Exelon® patch applied daily for 7 days in healthy adult male and female subjects.To assess...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON40916

Source
ToetsingOnline

Brief title
Rivastigmine transdermal patch study.

Condition

- Dementia and amnestic conditions

Synonym
Dementia

Research involving
Human

Sponsors and support

Primary sponsor: Noven Pharmaceuticals, Inc.
Source(s) of monetary or material Support: Farmaceutische Industrie.

Intervention

Keyword: Dementia, Rivastigmine, Transdermal patch

Outcome measures

Primary outcome

Pharmacokinetics: plasma concentrations and PK-parameters.

Dermal evaluations, patch adhesion, amount of adhesive residue application

site, difficulty of patch removal, residual drug analysis.

Safety: AE's, vital signs, ECG, clinical laboratory assessments, physical

examination.

Secondary outcome

Not applicable.

Study description

Background summary

The 7-day rivastigmine transdermal system (RTS) is a new, investigational transdermal application form (transdermal means: patch for administration via the skin) of the known drug rivastigmine that may eventually be used for the

treatment of mild to moderate Alzheimer*s disease related dementia and Parkinson*s disease related dementia.
Rivastigmine blocks the degradation of acetylcholine, a compound involved in signal transduction between nervous cells decreasing the symptoms of dementia. The 7-day RTS being studied will be worn for 7 continuous days and has not been registered as an administration form. Rivastigmine has been given to humans using a transdermal patch before. The Exelon® transdermal patch contains rivastigmine is worn for 24 hours, and is a registered drug.

Study objective

To compare the rate and extent of rivastigmine absorption from two different formulations of 7-day rivastigmine transdermal systems (7-day RTS) with 24-hour Exelon® patch applied daily for 7 days in healthy adult male and female subjects.

To assess skin irritation, discomfort, patch adhesion and adhesive residue of 7-day RTS and Exelon® transdermal patch in healthy adult male and female subjects.

To assess the safety and tolerability of 7-day RTS and Exelon® transdermal patch in healthy adult male and female subjects.

Study design

The study will consist of 3 periods during which the volunteer will stay in the clinical research center in Zuidlaren for 10 days (9 nights). The time interval between the different periods is at least 5 days between leaving the clinical research center and entering the clinical research center for the next period.

The volunteers are expected at the clinical research center at 14:00 h in the afternoon prior to the day of administration of study medication.

They willl leave the clinical research center on Day 9 of each period (Day 1 is the day of administration of study medication).

The participation to the entire study, from pre-study screening until the post study screening, will be maximally 75 days.

Intervention

On Day 1 of each period RTS or Exelon® will be applied after a fasting period (no food or drinks) of at least 10 hours. The transdermal patches will be applied to the upper back. Per period the volunteer will receive 1 of the treatments. During the study they will receive all 3 treatments once. The sequence of the treatments will be determined by chance.

The Exelon® patch will be removed every morning and a new patch will be applied to a different site on the back. In the morning of Day 8 the (last) patch will be removed.

On Day 7 of each period the volunteer will also have to remain fasted for 10 hours before the time of patch application.

For all groups the fasting period on Days 1 and 7 will continue until 4 hours after the time of patch application. Then they will receive a lunch. During fasting and after patch application, the volunteer is allowed to drink water.

Study burden and risks

Procedures: pain, light bleeding, heamatoma, possibly an infection.

Rivastigmine has been on the market since 1998. Transdermal patches containing rivastigmine have been on the market from 2006 onwards. The 7-day RTS was tested in 1 earlier study with 18 subjects. The most important adverse events were headache, itch at the application site, hematoma at the site of the cannula and application site irritation.

Common side effects associated with the use of a transdermal system may include, but are not limited to, local skin irritation of the patch site (including redness, itching, or rash). The most common side effects of rivastigmine are nausea, vomiting, and diarrhea. Other side effects that are not as common are tremors, anorexia and dizziness.

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 or female subjects
18 - 65 years, inclusive
BMI 18.0 - 29.9 kg/m2
non-smoking
light skin color

Exclusion criteria

Suffering from: hepatitis B, cancer or HIV/AIDS. In case of participation in another drug study within 60 days before the start of this study or being a blood donor within 90 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):	16-04-2014
Enrollment:	18
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	27-03-2014
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	14-04-2014
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□000315□14-NL
CCMO	NL48570.056.14