A SINGLE-CENTER, OPEN-LABEL, RANDOMIZED, 3-WAY CROSSOVER STUDY TO COMPARE THE RATE AND EXTENT OF RIVASTIGMINE ABSORPTION FROM A 7 DAY RIVASTIGMINE TRANSDERMAL SYSTEM (7-DAY RTS) WITH AND WITHOUT OVERLAY WITH 24-HR EXELON® PATCH APPLIED DAILY FOR 7 DAYS IN HEALTHY MALE AND FEMALE SUBJECTS

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The purpose of the study is to investigate how quickly and to what extent rivastigmine is absorbed and eliminated from the body when administered RTS for 7 days (this is called pharmacokinetics) as well as the safety of RTS.

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

Summary

ID

NL-OMON38506

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, N34, 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: AEs, vital signs, ECG, clinical laboratory assessments, physical

examination

Secondary outcome

nvt

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

The purpose of the study is to investigate how quickly and to what extent rivastigmine is absorbed and eliminated from the body when administered RTS for 7 days (this is called pharmacokinetics) as well as the safety of RTS.

Study design

The study will consist of 3 periods during which you will stay in the clinical research center in Zuidlaren for 10 days (9 nights) for each period. 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. Your participation to the entire investigation, from pre-study screening to post study screening, will be maximally 73 days.

For each period you are expected at the clinical research center at 14:00 h in the afternoon prior to the day of drug administration. You will be required not to have consumed any food or drinks during the 4 hours prior to arrival in the clinical research center (with the exception of water).

You will leave the clinical research center on Day 9 of each period (Day 1 is the day of study drug administration).

7 to 10 days after discharge from the clinical research center after Period 3, you will be called for a short update.

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 your upper back. Per period you will receive 1 of the treatments. During the study you 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 your back. In the morning of Day 8 the (last) patch will be removed.

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

For all groups the fasting period on Day 1 and 7 will continue until 4 hours after the time of drug administration. Then you will receive a lunch. During fasting and after application of the study medication, you are allowed to drink water with the exception of 1 hour prior to until 1 hour after the time of drug administration.

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 will be applied to humans for the first time in this study, as a result to date adverse effects in humans have not been reported.

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

Public
Noven Pharmaceuticals, Inc.

Empire State Building, 350 Fifth Avenue, 37th Floor -
New York NY 10118
US
Scientific
Noven Pharmaceuticals, Inc.

Empire State Building, 350 Fifth Avenue, 37th Floor -
New York NY 10118
US

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
18-65 yrs, inclusive
BMI: 18.0-29.9 kg/m2, inclusive
non-smoking
light skin color

Exclusion criteria

Suffering from hepatitis B, hepatitis C, 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 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):	08-04-2013
Enrollment:	18
Type:	Anticipated

Medical products/devices used

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

Ethics review

Approved WMO

Date:	03-04-2013
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Approved WMO

Date:	08-04-2013
Application type:	First submission
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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	EUCTR2013-000989-11-NL
CCMO	NL44242.056.13