

# 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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Dementia and amnestic conditions
<b>Study type</b>	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:** pharmaceutische 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

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2-05-2025

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, hematoma, 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**

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US

### **Scientific**

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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

18-65 yrs, inclusive

BMI: 18.0-29.9 kg/m<sup>2</sup>, 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  
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	EUCTR2013-000989-11-NL
CCMO	NL44242.056.13