A drug utilisation study in patients treated with EXELON®/PROMETAX® (rivastigmine) transdermal patch

First published: 24/09/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7537

Study ID

27280

DARWIN EU® study

No

Study countries

- ☐ Germany
- ☐ Greece
- ☐ Portugal
- ☐ United Kingdom

Study description

Exelon/Prometax is indicated for mild to moderately severe Alzheimer’s dementia. Postmarketing adverse event reports have documented instances of medication misuse and medication error. EMA/CHMP requested development of educational materials to help minimise multiple patch use. The aim of this DUS is to assess the extent of inappropriate use of Exelon/Prometax patches following introduction of this new educational materials and to assess titration patterns. This proposed DUS is a prospective, non-interventional, multinational, multicentre, cohort field post-authorization safety study (PASS) of physician prescribing patterns and patient use of Exelon/Prometax patches. The study will be implemented in EU, e.g., Germany, Greece, Portugal, United Kingdom. The total study population is ~800 patients. Total duration of patient data collection will be up to 11 months for each patient.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

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Institution

Multiple centres

Multiple centres: 80 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Novartis Clinical Disclosure Officer

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/05/2013

Actual: 14/05/2013

Study start date

Planned: 17/11/2014

Actual: 12/11/2014

Data analysis start date

Planned: 17/11/2015

Actual: 17/11/2015

Date of final study report

Planned: 13/12/2018

Actual: 14/11/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Novartis

Study protocol

cena713d2409-redacted protocol.pdf(756.01 KB)

ena713d2409-v02--protocol amendment redacted.pdf(1.06 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Other study registration identification numbers and links

CENA713D2409

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

To assess appropriate use and estimate amount and type of inappropriate drug use of all doses of Exelon/Prometax patches as recorded by patients and/or their assistantsEstimation of inappropriate use will be stratified by characteristics of patients, patient assistants, and physicians, if possibleTo assess titration patterns of Exelon/Promet

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Dementia Alzheimer's type

Population studied

Short description of the study population

Physician prescribing patterns and patient use of Exelon/Prometax patches
To be eligible for the study, patients were required to meet all of the following criteria:
1. Currently using Exelon/Prometax patch (i.e., 4.6 mg/24 hour [5 cm2], 9.5 mg/24 hour [10 cm2], or 13.3 mg/24 hour [15 cm2]) or where an independent decision has been made by their health care professional to initiate treatment with Exelon/Prometax patch at baseline. In Germany (as requested by BfArM) the following will also apply: Exelon/Prometax patch treatment to be in

accordance with the approved SmPC.
2. Have an assistant who is willing to participate in the study and is able to understand and comply with study procedures in the local language and able to provide informed consent for themselves. The patient assistant does not need to be a primary or formal caregiver and can include a family member or other individual who helps with the patient’s activities of daily living.
3. Able to provide informed consent to participate in the study or have a legal representative who is willing and able to provide informed consent on their behalf.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

600

Study design details

Outcomes

The outcomes of interest include inappropriate use, titration patterns, and perceived usefulness of the Exelon/Prometax patch Patient Reminder Card (e.g. the new educational material).

Data analysis plan

The main analysis will estimate (with 95% confidence intervals) the percentage of patients with inappropriate use and the percentage of days with

inappropriate use. Results will be presented both for overall/any inappropriate use as well as by type of inappropriate use (e.g. multiple patches, incorrect anatomical skin site). Results will be stratified by country and other logical variables, such as patient age, severity of dementia, time since diagnosis of dementia, previous patch use, completeness of the Medication Record Sheets, and practice/physician characteristics, where possible.Titration will be described by summarising the time elapsed from lower to higher dose and by describing the main indications for dose change. Elapsed time, as summary measures or distributions, will be presented separately for each type of dose change (e.g. oral to patch, each patch dose to next higher dose, change from higher dose to lower dose).

Documents

Study results

ena713d2409--legacy-clinical-study-report_Redacted2.pdf(6.45 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No