A Post-Authorisation Safety Study to Evaluate the Effectiveness of VIZAMYL™ Reader Training in Europe

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Study Finalised

Administrative details

EU PAS number

EUPAS24735

Study ID

26709

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Germany
- [ ] Italy
- [ ] Netherlands

Spain

Study description

This study, designed in response to requests from EMA, will assess effectiveness of the electronic training programme (ETP) in clinical practice by determining the diagnostic accuracy of the visual image interpretations made by clinical readers (i.e. readers who mainly interpret nuclear medicine images in clinical practice rather than in research) in European countries where VIZAMYL™ is commercially available and where high use is expected during the study period. Each reader will interpret images from his/her site, for a total of at least 200 images across all sites. The standard of truth (SOT) will be the majority blinded visual interpretation of 5 expert readers who will independently review the same ≥200 images.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 15 centres are involved in the study

Contact details

Study institution contact

Paul Sherwin paulsherwin@ge.com

Study contact

paulsherwin@ge.com

Primary lead investigator

Paul Sherwin

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 04/09/2018

Actual: 12/10/2018

Study start date

Planned: 10/10/2018

Actual: 26/10/2018

Date of final study report

Planned: 09/04/2020

Actual: 16/03/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GE HealthCare

Study protocol

GE-067-027 CPR_V5.pdf (1.63 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Assessment Reading Training Programme

Data collection methods:

Primary data collection

Main study objective:

Assess effectiveness of the VIZAMYL™ reader training programmes (in-person or electronic) in Europe by estimating the diagnostic accuracy, sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of the visual interpretation of VIZAMYL™ images obtained in clinical practice.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Phase 4, post-authorisation safety study

Study drug and medical condition

Medical condition to be studied

Dementia Alzheimer's type

Population studied

Short description of the study population

The study population included patients aged 18 years or older diagnosed with Alzheimer’s disease (AD) and other causes of cognitive impairment who had been referred by the physician for a clinically indicated VIZAMYL™ PET brain scan in European countries.
Inclusion criteria:
1. The subject is an adult (aged 18 years or older) of any race or gender and has been referred for a VIZAMYL™ PET brain scan as part of the assessment of his/her cognitive impairment.
2. The VIZAMYL™ scan was ordered as part of the clinical care of the subject and is not exclusively for a clinical trial.
3. The subject, or his/her legally authorised representative, is willing and able to sign consent for use of their de-identified VIZAMYL™ PET images and associated anatomic images (brain CT and/or MRI) used in the interpretation of the VIZAMYL™ images as well as deidentified demographic information.

Exclusion criteria:
1. The subject (or representative) is not willing to consent to their de-identified images and other data being used in this study.

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)

Special population of interest

Other

Special population of interest, other

Patients with Alzheimer’s disease

Estimated number of subjects

200

Study design details

Outcomes

Diagnostic accuracy (point estimates and exact 95% CIs) determined across all images (at least 200 images), as indicators of the collective proficiency of the clinical readers at interpreting VIZAMYL™ PET images. Diagnostic accuracy will give an indication of the overall image interpretation error rate (1 minus diagnostic accuracy). Sensitivity, specificity, PPV, and NPV.

Data analysis plan

Diagnostic accuracy, sensitivity, specificity, PPV, and NPV value will be determined for each reader, and reported as point estimates with exact 95% confidence intervals (CIs).

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

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