Post-Authorisation Survey of Nuclear Medicine Physicians and Radiologists in Europe to Evaluate Trends and Patterns in VIZAMYL™ Use in Everyday Clinical Practice in the EU

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Study | Finalised

Administrative details

EU PAS number

EUPAS25167

Study ID

26712

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Belgium

- [ ] Finland
- [ ] Germany
- [ ] Italy
- [ ] Slovakia
- [ ] Sweden

Study description

This drug utilisation study, is designed in response to request from EMA, will retrospectively assess the actual use of VIZAMYL PET scans in the everyday clinical settings and determine the level of off-label use in Europe. The study will retrospectively survey VIZAMYL readers in European countries where VIZAMYL is commercially available and where high use is expected during the study period to determine trends and patterns of VIZAMYL use in everyday clinical practice.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 50 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: 03/12/2018

Actual: 12/03/2018

Study start date

Planned: 12/02/2019

Actual: 01/07/2020

Date of final study report

Planned: 20/08/2020

Actual: 29/04/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

GE HealthCare

Study protocol

GE-067-028 CPR v5.pdf (1.45 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:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To retrospectively determine post-authorisation use of VIZAMYL in everyday clinical practice in the EU.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective post-authorisation study

Study drug and medical condition

Medical condition to be studied

Dementia Alzheimer's type

Population studied

Short description of the study population

A survey of physicians practicing nuclear medicine or radiologist in at least one of the target countries, had reviewed at least three VIZAMYL™ scans.

Age groups

- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)

Special population of interest

Other

Special population of interest, other

Patients with Alzheimer’s disease

Estimated number of subjects

0

Study design details

Outcomes

Summary across survey respondents of reported percentage of patients referred for a VIZAMYL scan for the indication listed in the SmPC. This will be determined separately for each survey round (3 rounds, conducted at 12-month intervals). To retrospectively describe use in everyday clin. practice with regard to: Indication, admin. dose of radioactivity, body region imaged, time from dosing to scan initiation, duration of scanning, type of other images used to assist in interpret. of images, percent. of patients with a contraind who were scanned and not scanned, percent. of readers who have compl training in interpret of PET images

Data analysis plan

Tabulations of summary statistics, graphical presentations, and statistical analyses will be performed using SAS software, Version 9.3 or higher. Descriptive statistics for continuous data in summary tables will include the number of subjects in the analysis (n), mean, standard deviation, median, and range (minimum, maximum). Descriptive statistics for categorical data in summary tables will include counts and percentages. All data entered into the database will be provided in separate data listings showing individual subject values. The planning and reporting of statistical analysis will be carried out as described in the Sponsor and CRO’s standard operating procedures governing clinical studies. Details of the analysis will be provided in the Statistical Analysis Plan. Missing values will not be substituted by estimated values, but treated as missing in the statistical evaluation. All data from all subjects enrolled and imaged in the study will be included in all listings.

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

All survey data will be obtained from the web-based survey forms. Eligible physicians who agree to participate will be selected and demographic information about them will be collected. They will answer a series of survey questions about their recollection of personal experience using VIZAMYL in everyday clinical practice.

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