European Drug Usage Survey for Amyvid (I6E-MC-AVBF)

First published: 12/12/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/24810

EU PAS number

EUPAS6736

Study ID

24810

DARWIN EU® study

No

Study countries

- ☐ Italy
- ☐ Spain
- ☐ United Kingdom

Study description

This is a survey of physicians who refer patients for Amyvid PET scans. This study seeks to establish the usage patterns of Amyvid in European clinical practice.

Study status

Finalised

Research institutions and networks

Institutions

Real World Evidence Solutions, IMS Health

France

First published: 06/09/2011

Last updated: 20/08/2024

Institution | Other

Contact details

Study institution contact

Claudia Salinas

Study contact

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Primary lead investigator

Claudia Salinas

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 15/12/2014

Actual: 15/12/2014

Study start date
Planned: 15/12/2014

Actual: 17/12/2014

Date of final study report
Planned: 01/06/2017

Actual: 28/10/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

European drug usage survey for Amyvid I6E-MC-AVBF - redacted approved protocol.pdf(1.04 MB)

AVBF PASS Protocol_Redacted.pdf(629.1 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

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 the usage patterns of Amyvid in European clinical practice,To assess the level of off-label use in European clinical practice.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(V09AX05) florbetapir (18F)

florbetapir (18F)

Medical condition to be studied

Dementia Alzheimer's type

Population studied

Short description of the study population

Healthcare providers who were referrers for Amyvid PET scans with following criteria:

• physicians in active clinical practice

• hospital- or office-based,

• who practice in an EU country

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 Dementia Alzheimer's type

Estimated number of subjects

100

Study design details

Data analysis plan

Reasons for the Amyvid referral will be summarized using responses to the survey questions. The level of off-label use will be reported for each relevant question as a proportion of the total responses and as the total number of questions consistent with off-label use. Results will also be analysed by temporal period (1, 2, or 3 years elapsed since commercial launch of Amyvid) to evaluate if there are trends in patterns of Amyvid use. Reasons for non-response will be evaluated to assess the potential existence of selection bias. Additional information is available in the report.

Documents

Study results

AVBF PASS FSR_Redacted.pdf(943.24 KB)

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

Unknown