Evaluation of Effectiveness of Amyvid Reader Training (I6E-AV-AVBE)

First published: 15/12/2015

Last updated: 31/01/2017

Study Ongoing

Administrative details

EU PAS number

EUPAS11867

Study ID

17582

DARWIN EU® study

No

Study countries

Italy

Spain

United Kingdom

Study description

Florbetapir 18F solution for injection (Amyvid) is a member of a class of diagnostic radiopharmaceuticals for positron emission tomography (PET) imaging. Because physicians are likely to be unfamiliar with florbetapir scan interpretation, reader training programmes have been developed, tested, and will be provided as a component of the risk management system for the product. While such programmes have been successful in training readers within the setting of clinical trials, it is important to assess the effectiveness of these reader training methods when used by physicians as part of routine clinical practice. The objective of this study will address this by assessing the effectiveness of the different florbetapir training methods agreed in the European clinical setting to ensure that accuracy in routine practice is in line with expected accuracy from the clinical trials.

Study status

Ongoing

Research institutions and networks

Institutions

Eli Lilly and Company

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Institution

Avid Radiopharmaceuticals,Inc.

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Anupa Arora

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 16/12/2015

Actual: 03/02/2016

Study start date

Planned: 17/02/2016

Actual: 11/02/2016

Data analysis start date

Planned: 31/07/2017

Date of interim report, if expected

Planned: 30/06/2017

Date of final study report

Planned: 31/03/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Eli Lilly and Company

Study protocol

2016-01-29-AVBE-Non_interventional PASS Protocol_REDACTED.pdf (285.44 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 type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

(1) to assess the frequency of reading errors in routine clinical practice after training implementation, and (2) to assess reader understanding of, and compliance with, the indication with respect to image interpretation after training implementation.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Cross-sectional assessment of specialist physicians who read florbetapir PET scans in routine EU medical practice at two points in time after commercial launch.

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

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

75

Study design details

Data analysis plan

No formal a priori hypothesis will be tested in this study. Scan interpretation results from clinical practice readers will be compared to results from an expert consensus panel on the same scan using accuracy, sensitivity, specificity, error rate, false negative rate, false positive rate with corresponding 95% confidence intervals based on the Wilson score method. Reader understanding of the florbetapir indication will be calculated as the proportion of responses correctly identifying example reports as consistent/inconsistent with the EU Summary of Product Characteristics.

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

A set of 40 florbetapir PET scans will be randomly chosen from the EU sites participating in the 18F AV-45-A18 clinical study (EudraCT#2012-002595-13, clinicaltrials.gov #NCT01703702).

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