Pattern of use, safety and tolerability of the diagnostic agent NeuraCeqTM in European clinical practice: A cross-sectional, retrospective, non-interventional post-authorisation safety study (PASS) (FBB-01_03_13)

First published: 16/06/2016

Last updated: 10/03/2021

Study Finalised

Administrative details

EU PAS number

EUPAS13366

Study ID

39896

DARWIN EU® study

No

Study countries

France
Germany
Italy
Spain
United Kingdom

Study description

Cross-sectional, non-interventional retrospective survey of physicians who have referred at least one patient for a clinical NeuraCeqTM PET scan in European countries where the radiopharmaceutical is commercially available. Collection of study data can be conducted using a paper-based questionnaire. The survey will be conducted in countries with a large population including Italy, France, Germany, Spain and United Kingdom. These countries become eligible for study participation once at least 10 Neuraceq doses have been applied clinically. The individual referring site becomes eligible if at least one scan has been ordered for the evaluation of a patient in a clinical practice setting. Enrollment will commence once a country becomes eligible for study participation and an individual prescriber has at least sent one referral for NeuraCeqTM PET scan. The study will continue for 3 years or a target enrollment of 400 patients and 100 physicians. Upon a twice-yearly recruitment analyses in the first two years, survey participation may be adapted. Additional countries meeting inclusion criteria may be added to support minimal survey enrollment (defined as obtaining at least 100 patient reports from at least 20 referring physicians).

Study status

Finalised

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Andrew Stephens

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 16/03/2016

Study start date

Planned: 31/10/2016

Actual: 21/12/2016

Data analysis start date

Planned: 31/01/2017

Actual: 01/11/2017

Date of interim report, if expected

Planned: 30/12/2016

Actual: 30/12/2017

Date of final study report

Planned: 30/09/2020

Actual: 03/09/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Piramal Imaging Ltd.

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

1.Describe the Usage Pattern of NeuraCeq in routine clinical practice2.Monitor off-label use of in cognitively normal and in persons with Down’s syndrome3.Monitor the safety profile of NeuraCeq in a real life population including:- patients with renal impairment - patients with hepatic impairment- potential effects of drug-drug interactions- occurence of hypersensitivity reactions.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Physicians survey, Post-authorization safety study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(V09AX06) florbetaben (18F)

florbetaben (18F)

Medical condition to be studied

Dementia Alzheimer's type

Population studied

Short description of the study population

Physicians who have referred at least one patient for a clinical NeuraCeqTM PET scan in European countries where the radiopharmaceutical is commercially available

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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

Renal impaired

Hepatic impaired

Estimated number of subjects

400

Study design details

Data analysis plan

No a priori hypothesis has been formulated and the analysis will be purely descriptive. Variables collected during the study will mainly be categorical, such as the reason why patients are receiving imaging, or whether imaging was done in accordance with the SmPC or off-label.The power calculation for this study is based on defining an acceptable width for the confidence intervals for the percentage of patients with off label use. Overall study population will be analysed and reported AEs compared to the Phase III data. Data for patients with renal or hepatic impairment will be analyzed with regards to reported AEs and this will be compared to the overall study population to identify a potential difference. Analysis and comparison of the proportion of patients taking concomitant medications including disulfiram, and those with co-morbidities vs. those patients who are not receiving medication and without co-morbidities, will be conducted.

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

The study-related data will be collected with a paper-based CRF.Data sources are:Information provided by the referring physicians, including information the referring physician received from the nuclear medicine physician.

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