A prospective observational study to assess effectiveness of the training and risk minimisation measures recommended for the usage of the diagnostic agent NeuraCeqTM in the post-authorisation clinical situation: A post-authorisation safety study (PASS)

First published: 21/01/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS12145

Study ID

39964

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Spain
- [ ] United Kingdom

Study description

Study to monitor the frequency of reading errors of Florbetaben (18F) PET scan images after completion of NeuraCeq PET scan reading training. Participating Nuclear medicine physicians will be asked to take a test assessment consisting of 20 Neuraceq PET cases including positive and negative cases. These test cases are presented immediately after the reader training as well as 6 months later. The test scans will include cases with histopathology confirmation of the diagnosis, and longitudinal clinical data in MCI subjects, as well as scans from young cognitively normal healthy volunteers. Test scan assessments will be matched against scan read outs made by 2 independent experts, who agreed on the scan report as positive or negative. Study on effectiveness of risk minimisation measures as recommended in the NeuraCeqTM RMP to be assessed for the same 100 nuclear medicine physicians who underwent reader training and agreed to participate in the study. Effectiveness of the risk minimisation measure is based on results of a questionnaire, which evaluates compliance with the recommended risk minimisation measures. The Nuclear Medicine physicians will populate the questionnaire twice, first immediately after inclusion into the study and again 6 months later. If scan reader training has been performed more than one month before study inclusion, label information will be retrained.

Study status

Finalised

Contact details

Study institution contact

Andrew Stephens f.elsholz@life-mi.com

Study contact

f.elsholz@life-mi.com

Primary lead investigator

Andrew Stephens

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/12/2015

Study start date

Planned: 31/03/2016

Actual: 24/03/2016

Data analysis start date

Planned: 15/03/2017

Actual: 01/06/2017

Date of interim report, if expected

Planned: 30/06/2017

Actual: 28/06/2017

Date of final study report

Planned: 29/03/2019

Actual: 01/02/2019

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

Safety study (incl. comparative)

Other

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

Effectiveness evaluation of training material

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

1. To monitor effectiveness of nationally approved material to enable PET scan readers to correctly classify abnormal or normal Florbetaben (18F) tracer uptake in the brain.2. To monitor the understanding and compliance of readers with the approved indication, limitation of use and interpretation of Florbetaben (18F) images.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective observational study to assess effectiveness of the training and risk minimisation measures recommended for the usage of the diagnostic agent NeuraCeqTM in the post-authorisation clinical situation, post-authorisation 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 order Neuraceq for clinical usage after marketing authorisation in Europe.

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

100

Study design details

Data analysis plan

Due to the exploratory nature of the study, the analysis will be mostly descriptive. For categorical data, absolute and relative frequencies (in %) will be calculated. Quantitative data will be shown by descriptive statistics (mean, SD, min, max, median, quartiles). 95%-confidence intervals will be computed for frequencies and means as appropriate. For both primary variables the variation among the readers will be addressed by displaying the frequency distribution of readers on the number of reading errors resp. incorrect answers (e.g. number of readers who show reading errors 0-10%, >10-20%, >20-30% etc.).

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

Visual assessment results of 20 PET scan cases previously assessed by two independent experts (to achieve the first goal, the primary objective 1 - effectiveness of training material).Answers of a multiple choice questionnaire

(to achieve the second goal, the primary objective 2 - monitoring the effectiveness of risk minimisation measures.

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