PRospective obsErvational Study to quantify thE buRden of illness of Vasospasm and delayed cErebral ischaemia (PRESERVE)

First published: 30/08/2022

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS48706

Study ID

49584

DARWIN EU® study

No

Study countries

France

Study description

**This study was terminated prematurely for reasons unrelated to any safety or patient-related concerns, as no data was collected no report will be produced ** This is a prospective, nationwide, multi-centre observational cohort study which aims to assess the humanistic burden of illness associated with the development of delayed cerebral ischaemia (DCI) following aneurysmal subarachnoid hemorrhage (aSAH). The study will utilise survey methods to administer validated and bespoke questionnaires to patients with aSAH and their principal caregiver. A total of 400 participants with aSAH will be recruited by eleven centres across France. Participating hospitals will provide details regarding the aSAH event and clinically relevant details by completing an electronic case report form at patient hospital discharge. After discharge, patient and caregiver questionnaires will be administered at 3-, 6- and 12-months following date of patient aneurysmal securing procedure. The participants functional status, activities of daily living, employment and productivity, as well as quality of life will be assessed. In addition, the participant’s caregiver burden and work and productivity will be assessed.

Study status

Finalised

Research institutions and networks

Institutions

Evidence and Access/Analytica Laser, Certara

France

United Kingdom (Northern Ireland)

First published: 24/05/2021

Last updated: 06/03/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Multiple centres: 11 centres are involved in the study

Networks

BELIEVE Scientific Committee

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Louis Puybasset

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 23/11/2021

Actual: 23/11/2021

Study start date
Planned: 14/11/2022

Actual: 06/02/2023

Data analysis start date
Planned: 01/06/2024

Actual: 06/02/2023

Date of final study report
Planned: 31/12/2024

Actual: 06/02/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Idorsia Pharmaceuticals Ltd

Regulatory

Was the study required by a regulatory body?

No

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:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To assess and compare the humanistic burden of illness associated with the development of delayed cerebral ischaemia following aneurysmal subarachnoid hemorrhage among patients and their caregivers.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Other

Non-interventional study design, other

Prospective, nationwide, multi-centre observational study

Study drug and medical condition

Medical condition to be studied

Subarachnoid haemorrhage

Additional medical condition(s)

Aneurysmal subarachnoid hemorrhage

Population studied

Short description of the study population

Patients with aneurysmal subarachnoid hemorrhage (aSAH) identified from 11 centres across France.

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 subarachnoid haemorrhage

Estimated number of subjects

400

Study design details

Outcomes

The following patient outcomes will be assessed and compared at each follow-up time-point, unless otherwise stated: - Functional impairment - Cognitive impairment - Health-related quality of life - Activities of daily living - Mood - Return to work among employed patients at 12 months - Return to school/education among patients at 12 months - Work productivity/absenteeism at 12 months, The following caregiver outcomes will be assessed and compared at each follow-up time-point, unless otherwise stated: - Health-related quality of life - Caregiver subjective burden - Caregiver objective burden - Mood - Return to work, where relevant at 12 months - Return to school/education, where relevant at 12 months - Work productivity/absenteeism, where relevant at 12 months

Data analysis plan

Descriptive statistics will be used to describe and compare participant demographic and clinical characteristics according to patient DCI status. Propensity score methods will be used to balance differences between patients and the caregivers of patients who did and did not develop DCI. Propensity scores will be derived for each participant using a logistic regression model

including pre-specified confounders such as age, World Federation of Neurosurgical Societies grade, Modified Fisher scale, aneurysm size, aneurysm-securing procedure. Thereafter, the groups will be balanced using the Inverse Probability of Treatment Weighting (IPTW). Appropriate models (mixed effects logistic regression for binary variables, mixed effects linear regression model for continuous variables and count or rate variables) will be used to compare patient and caregiver outcomes according to DCI status, accounting for IPTW.

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.

Composition of steering group and observers

Composition Scientific Committee.pdf (34.96 KB)

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Prospective caregiver-based data collection Medical chart review

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