A REtrospective Study to discOver the economic impLications of Vasospasm and delayed cErebral ischaemia (RESOLVE)

First published: 16/12/2022

Last updated: 02/06/2023

Study Finalised

Administrative details

EU PAS number

EUPAS50204

Study ID

50205

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 retrospective, nationwide, multi-centre observational cohort study which aims to assess the healthcare resource utilization (HCRU) and clinical outcomes associated with the development of delayed cerebral ischaemia (DCI) following aneurysmal subarachnoid haemorrhage (aSAH). The study will use existing patient data held in medical charts and the Système National des Données de Santé (SNDS), the French national healthcare database. A total of 300 patients with aSAH will be recruited by eleven centres across France via consecutive stratified recruitment to obtain an approximately equal number of DCI and non-DCI patients. Physicians will be asked to extract relevant retrospective data from medical charts of patients admitted to their centre between 1st January 2017 and 31st December 2018. Patient chart data will be linked with data from the SNDS to obtain more comprehensive HCRU data and longer-term data on patient outcomes including mortality.

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

BELIEVE.project@certara.com

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: 15/01/2023

Actual: 06/02/2023

Data analysis start date
Planned: 01/06/2023

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 topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

To assess and compare hospital length of stay in patients with and without delayed cerebral ischaemia following aneurysmal subarachnoid haemorrhage

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective, 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 subarachnoid haemorrhage identified from the medical charts and the Système National des Données de Santé (SNDS), the French national healthcare database.

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

300

Study design details

Outcomes

The following patient outcomes will be assessed and compared: - Overall hospital length of stay - Intensive care unit length of stay - Length of stay in acute and subacute hospital settings (excluding inpatient rehabilitation centre stays) length of stay - Inpatient rehabilitation centre length of stay, The following patient outcomes will be assessed: - All-cause re-admissions to hospital - Imaging/diagnostic tests undertaken - Recue therapy requirements - Discharge location - Outpatient rehabilitation centre visits - All cause mortality - Direct costs - Indirect costs

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Data analysis plan

Descriptive statistics will be used to describe and compare patient demographic and clinical characteristics according to patient DCI status. Propensity score methods will be used to balance differences between patients who did and did not develop DCI. Propensity scores will be derived for each patient 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 healthcare resource utilization and patient 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_RESOLVE.pdf (35.08 KB)

Data sources

Data source(s), other

SNDS France

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

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