Study of Current Standard of Care in the U.S.: Incidence of postoperative events and associated costs among non-cardiac surgery patients exposed to neuromuscular blocking agents in the Cleveland Clinic (2005-2013)

First published: 01/05/2014

Last updated: 27/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6435

Study ID

22856

DARWIN EU® study

No

Study countries

United States

Study description

This study will provide information on the current burden of unmet needs, healthcare resource utilization and costs for patients exposed to neuromuscular blocking agents (NMBAs). The primary goal of the study is to understand in the population receiving NMBAs the demographic, past medical history and operative characteristics of patients who have postoperative complications and to assess their incidence as well as healthcare resource utilization and costs associated with these complications.

Study status

Finalised

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

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Last updated: 08/07/2025

Institution | Pharmaceutical company

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme Corp.

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 19/03/2014

Study start date

Planned: 01/06/2014

Actual: 01/07/2014

Data analysis start date

Planned: 28/02/2017

Actual: 28/02/2017

Date of final study report

Planned: 31/07/2017

Actual: 22/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme Corp.

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:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Other

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

This study aims at evaluating the unmet needs among patients using any neuromuscular blocking agents to support any drugs that could be used in this setting.

Data collection methods:

Secondary use of data

Main study objective:

This study will provide information on the current burden of unmet needs, healthcare resource utilization and costs for patients exposed to NMBAs.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(M03A) MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS

MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS

(M03AC03) vecuronium

vecuronium

(M03AC09) rocuronium bromide

rocuronium bromide

(N07AA) Anticholinesterases

Anticholinesterases

Population studied

Short description of the study population

Patients receiving any type of neuromuscular blocking agents and registered within the Cleveland Clinic Perioperative Health Documentation System between April 2005 and December 2013 will be included.

Patients will be excluded from the study if they have any of the following:

1. participating in Bridion clinical trials
2. incomplete data on age, gender, exposure to sedatives, opioids, antibiotics, AChE inhibitors, ASA status and type of surgery

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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

Hepatic impaired

Immunocompromised

Pregnant women

Renal impaired

Estimated number of subjects

200.000

Study design details

Outcomes

To identify patients with pre-specified post-operative events occurring in the Post Anesthesia Care Unit (PACU) and estimate the incidence among NMBA patients.To describe and compare the demographic, past medical history and operative characteristics of patients who experienced postoperative events and patients who did not experience any postoperative event. To describe the difference in healthcare resource utilization and costs between patients who have a postoperative complication and those who do not.To describe the difference in healthcare resource utilization and costs between patients with varying number of major and minor complications, as well as varying number of organ systems affected by major complications.

Data analysis plan

1. The incidence of specific pre-defined postoperative events occurring in the PACU will be assessed among patients receiving any NMBA as well as for subpopulations of patients.2. The difference in healthcare resource utilization between patients with any complication and those without a complication will be described after matching on predictive score of postoperative complications.

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 source(s), other

Cleveland Clinic Perioperative Health Documentation System United States

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

This is a retrospective cohort study of patients receiving neuromuscular blocking agents between April-2005 and December-2013 in the PHDS, an electronic medical record-based registry of non-cardiac surgical patients.

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