# 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

**First published:** 01/02/2024

**Last updated:** 08/07/2025

Institution | Pharmaceutical company

## Contact details

**Study institution contact**

Clinical Trials Disclosure Merck Sharp & Dohme Corp.
ClinicalTrialsDisclosure@merck.com

Study contact

ClinicalTrialsDisclosure@merck.com

**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

---

**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**

200000

# 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