Evaluate the Knowledge and Understanding of Anesthesiologists Use of BRIDION® solution for injection, 100 mg/mL sugammadex (as sugammadex sodium) in Canada

First published: 31/05/2018

Last updated: 27/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS24076

Study ID

29547

DARWIN EU® study

No

Study countries

Canada

Study description

This is an observational, cross-sectional survey of anesthesiologists in Canada to assess the level of understanding of the safe and appropriate use of BRIDIONTM. This knowledge and understanding (KAU) survey will help ensure the appropriate use of BRIDIONTM and evaluate the effectiveness of Merck-sponsored educational programs related to BRIDIONTM. The main objective of this study is to assess how anesthesiologists in Canada use BRIDIONTM as well as to evaluate how well anesthesiologists in Canada understand the safety and efficacy aspects of BRIDIONTM when administered to adult patients undergoing surgery.

Study status

Finalised

Contact details

Study institution contact

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

Study contact

ClinicalTrialsDisclosure@merck.com

Primary lead investigator

Annette Stemhagen

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 24/04/2017

Study start date
Planned: 31/07/2018

Actual: 31/07/2018

Data analysis start date
Planned: 02/10/2018

Actual: 04/10/2018

Date of final study report
Planned: 31/12/2018

Actual: 19/12/2018

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?

Yes

Is the study required by a Risk Management Plan (RMP)?

Non-EU RMP only

Methodological aspects

Study type

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

Knowledge and Understanding (KAU) Survey

Data collection methods:

Primary data collection

Main study objective:

To assess how anesthesiologists use BRIDIONTM and to evaluate how well anesthesiologists understand the safety and efficacy aspects of BRIDIONTM.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Observational survey

Study drug and medical condition

Medicinal product name, other

BRIDIONTM

Population studied

Short description of the study population

Anesthesiologists who have participated in Merck-sponsored educational programs related to BRIDION™ and anesthesiologists who have administered BRIDION™ in the past 12 months will also be included.

Participants must be anesthesiologists who meet at least one of the inclusion criteria below:

• Have been identified by Merck as having previously participated in Merck-sponsored educational programs related to BRIDION™.

• Have administered BRIDION™ in the past 12 months.

Prospective participants will not be accepted if they meet at least one of the exclusion criteria below:

• Have immediate family members who have ever worked for Merck Canada Inc., or any of its affiliates, or UBC.

• Do not fulfil either of the inclusion criteria.

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

200

Study design details

Data analysis plan

Data collected from the survey will be reported as descriptive statistics. Responses to each question relating to the knowledge and understanding of the use, safety and efficacy aspects, of BRIDIONTM, will be categorized as a “correct response” or an “incorrect response." Frequency distributions with exact binomial two-sided 95% confidence intervals (CIs) will be calculated for responses to questions that address the survey objectives.

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

A structured survey comprised of questions or statements with multiple response choices will be used to collect the survey data from anesthesiologists. The survey can be self-administered via the Internet through a secure website using an Electronic Data Capture (EDC) system or administered via telephone with a trained interviewer using the same EDC system for data collection.

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