Comparison of 2.0 mg/kg Sugammadex and Neostigmine at Reappearance of T2 in Chinese and European Subjects (Study 19.4.324)(P05768AM1)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00825812

First received: January 15, 2009
Last updated: October 30, 2015
Last verified: October 2015
History of Changes

Purpose

The present trial was set up to evaluate the efficacy and safety of 2.0 mg.kg-1 sugammadex compared to neostigmine administered at reappearance of T2 in Chinese and Caucasian subjects for registration purposes in China.

Condition	Intervention	Phase
Anesthesia, General Neuromuscular Blockade	Drug: Sugammadex Drug: neostigmine	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Single Blind (Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Multi-center, Randomized, Parallel-group, Active-controlled, Safety-assessor Blinded Trial, Comparing the Efficacy and Safety of 2.0 mg.Kg-1 Sugammadex With 50 µg.Kg-1 Neostigmine Administered at Reappearance of T2 After Rocuronium in Chinese and European ASA I-III Subjects Undergoing Elective Surgery Under Propofol Anesthesia

Resource links provided by NLM:

MedlinePlus related topics: Anesthesia

Drug Information available for: Atropine Neostigmine methylsulfate Atropine sulfate Rocuronium bromide Rocuronium Sugammadex Sugammadex sodium

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Time From Start of Administration of Investigational Medicinal Product (IMP) to Recovery of the T4/T1 Ratio to 0.9. [Time Frame: start of administration of sugammadex/neostigmine to recovery from neuromuscular blockade] [Designated as safety issue: No]

  Neuromuscular functioning was monitored by applying repetitive train of four (TOF) electrical stimulations to the ulnar nerve every 15 seconds and assessing twitch response at the adductor pollicis muscle. Nerve stimulation was to continue until the ratio of the magnitude of the fourth twitch (T4) to first twitch (T1) reached >= 0.9. The greater the T4/T1 ratio the greater the recovery from neuromuscular blockade, with a value of 1.0 representing full recovery. The primary analysis was the comparison between sugammadex & neostigmine among Chinese subjects; other comparisons were secondary.

Secondary Outcome Measures:

- Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.7 and 0.8. [Time Frame: start of administration of sugammadex/neostigmine to recovery from neuromuscular blockade] [Designated as safety issue: No]

  Neuromuscular functioning was monitored by applying repetitive TOF electrical stimulations to the ulnar nerve every 15 seconds and assessing twitch response at the adductor pollicis muscle. The greater the T4/T1 ratio the greater the recovery from neuromuscular blockade.

Enrollment:	308
Study Start Date:	January 2010
Study Completion Date:	September 2010
Primary Completion Date:	September 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Sugammadex in Caucasian Subjects At reappearance of T2 after the last dose of rocuronium, 2.0 mg.kg-1 sugammadex was administered.	Drug: Sugammadex After induction of anesthesia an intubation dose of 0.6 mg/kg rocuronium was administered. Maintenance doses of 0.1-0.2 mg/kg rocuronium intravenous (IV) could be administered if necessary. At reappearance of T2 after the last administration of rocuronium, an IV single bolus dose of 2.0 mg/kg sugammadex was administered. Other Name: Org 25969, Bridion®
Active Comparator: Neostigmine in Caucasian Subjects At reappearance of T2 after the last dose of rocuronium, 50 µg.kg-1 neostigmine (combined with 10-20 µg.kg-1 atropine, in a ratio ranging from 2.5:1 to 5:1) was administered.	Drug: neostigmine After induction of anesthesia an intubation dose of 0.6 mg/kg rocuronium was administered. Maintenance doses of 0.1-0.2 mg/kg rocuronium IV could be administered if necessary. At reappearance of T2 after the last administration of rocuronium, an IV single bolus dose of 50 µg/kg neostigmine (combined with 10-20 µg.kg-1 atropine, in a ratio ranging from 2.5:1 to 5:1) was administered. Other Name: Neostigmine with atropine
Experimental: Sugammadex in Chinese Subjects At reappearance of T2 after the last dose of rocuronium, 2.0 mg.kg-1 sugammadex was administered.	Drug: Sugammadex After induction of anesthesia an intubation dose of 0.6 mg/kg rocuronium was administered. Maintenance doses of 0.1-0.2 mg/kg rocuronium intravenous (IV) could be administered if necessary. At reappearance of T2 after the last administration of rocuronium, an IV single bolus dose of 2.0 mg/kg sugammadex was administered. Other Name: Org 25969, Bridion®
Active Comparator: Neostigmine in Chinese Subjects At reappearance of T2 after the last dose of rocuronium, 50 µg.kg-1 neostigmine (combined with 10-20 µg.kg-1 atropine, in a ratio ranging from 2.5:1 to 5:1) was administered.	Drug: neostigmine After induction of anesthesia an intubation dose of 0.6 mg/kg rocuronium was administered. Maintenance doses of 0.1-0.2 mg/kg rocuronium IV could be administered if necessary. At reappearance of T2 after the last administration of rocuronium, an IV single bolus dose of 50 µg/kg neostigmine (combined with 10-20 µg.kg-1 atropine, in a ratio ranging from 2.5:1 to 5:1) was administered. Other Name: Neostigmine with atropine

Eligibility

Ages Eligible for Study: 18 Years to 64 Years

Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

-Subjects who are willing to provide informed consent; be between 18 and 64 years old; are American Society of Anaesthesiology (ASA) class 1-3 (extremes included); scheduled for elective surgery under general anesthesia, allowing stable neuromuscular monitoring, which requires neuromuscular blockade using rocuronium; be compliant with the dose/visit schedules, and use an accepted method of contraception (if applicable).

For China only: Subjects of Chinese descent born in China, never emigrated out of China and have a Chinese home address. For Europe only: Subjects of Caucasian descent born in Europe, never emigrated out of Europe and have a European home address.

Exclusion Criteria:

-Subjects with expected difficult intubation, neuromuscular disorders affecting neuromuscular blockade, significant renal/hepatic dysfunction, use of a tourniquet, (family) history of malignant hyperthermia, allergy to general anesthesia medications, contraindication to study drugs, breast feeding, pregnant, participation in previous or new trials, a clinically significant condition that may interfere with the trial, or membership in the (family of) study/sponsor staff.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

No Contacts or Locations Provided

More Information

Publications:

Wu X, Oerding H, Liu J, Vanacker B, Yao S, Dahl V, Xiong L, Claudius C, Yue Y, Huang Y, Abels E, Rietbergen H, Woo T. Rocuronium blockade reversal with sugammadex vs. neostigmine: randomized study in Chinese and Caucasian subjects. BMC Anesthesiol. 2014 Jul 12;14:53. doi: 10.1186/1471-2253-14-53. eCollection 2014.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00825812 History of Changes
Other Study ID Numbers:	P05768 19.4.324
Study First Received:	January 15, 2009
Results First Received:	July 22, 2011
Last Updated:	October 30, 2015
Health Authority:	Denmark: Danish Medicines Agency China: Food and Drug Administration

Additional relevant MeSH terms:

Atropine	Molecular Mechanisms of Pharmacological Action
Neostigmine	Muscarinic Antagonists
Rocuronium	Mydriatics
Adjuvants, Anesthesia	Neuromuscular Agents
Anti-Arrhythmia Agents	Neuromuscular Blocking Agents
Anti-Asthmatic Agents	Neuromuscular Nondepolarizing Agents
Autonomic Agents	Neurotransmitter Agents
Bronchodilator Agents	Parasympatholytics
Cardiovascular Agents	Parasympathomimetics
Central Nervous System Agents	Peripheral Nervous System Agents
Cholinergic Agents	Pharmacologic Actions
Cholinergic Antagonists	Physiological Effects of Drugs
Cholinesterase Inhibitors	Respiratory System Agents
Enzyme Inhibitors	Therapeutic Uses

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Results First Received: July 22, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Parallel Assignment; Masking: Single Blind (Outcomes Assessor); Primary Purpose: Treatment
Conditions:	Anesthesia, General Neuromuscular Blockade
Interventions:	Drug: Sugammadex Drug: neostigmine

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
308 participants were randomized

Reporting Groups

	Description
Sugammadex in Caucasian Subjects	At reappearance of T2 after the last dose of rocuronium, 2.0 mg.kg-1 sugammadex was administered.
Neostigmine in Caucasian Subjects	At reappearance of T2 after the last dose of rocuronium, 50 µg.kg-1 neostigmine (combined with 10-20 µg.kg-1 atropine, in a ratio ranging from 2.5:1 to 5:1) was administered.
Sugammadex in Chinese Subjects	At reappearance of T2 after the last dose of rocuronium, 2.0 mg.kg-1 sugammadex was administered.
Neostigmine in Chinese Subjects	At reappearance of T2 after the last dose of rocuronium, 50 µg.kg-1 neostigmine (combined with 10-20 µg.kg-1 atropine, in a ratio ranging from 2.5:1 to 5:1) was administered.

Participant Flow: Overall Study

	Sugammadex in Caucasian Subjects	Neostigmine in Caucasian Subjects	Sugammadex in Chinese Subjects	Neostigmine in Chinese Subjects
STARTED	**29**	**32**	**126**	**121**
TREATED	**29**	**31**	**120**	**111**
COMPLETED	**29**	**31**	**120**	**111**
NOT COMPLETED	**0**	**1**	**6**	**10**
Never entered follow up	**0**	**0**	**0**	**1**
Adverse Event	**0**	**0**	**0**	**1**
Subject withdrew consent	**0**	**0**	**3**	**2**
Non-compliance with protocol	**0**	**0**	**0**	**1**
Administrative	**0**	**1**	**3**	**5**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Sugammadex in Caucasian Subjects	At reappearance of T2 after the last dose of rocuronium, 2.0 mg.kg-1 sugammadex was administered.
Neostigmine in Caucasian Subjects	At reappearance of T2 after the last dose of rocuronium, 50 µg.kg-1 neostigmine (combined with 10-20 µg.kg-1 atropine, in a ratio ranging from 2.5:1 to 5:1) was administered.
Sugammadex in Chinese Subjects	At reappearance of T2 after the last dose of rocuronium, 2.0 mg.kg-1 sugammadex was administered.
Neostigmine in Chinese Subjects	At reappearance of T2 after the last dose of rocuronium, 50 µg.kg-1 neostigmine (combined with 10-20 µg.kg-1 atropine, in a ratio ranging from 2.5:1 to 5:1) was administered.
Total	Total of all reporting groups

Baseline Measures

	Sugammadex in Caucasian Subjects	Neostigmine in Caucasian Subjects	Sugammadex in Chinese Subjects	Neostigmine in Chinese Subjects	Total
Number of Participants [units: participants]	29	31	120	111	291
Age [units: years] Mean (Full Range)	52.0 (27 to 64)	51.9 (34 to 63)	39.9 (19 to 63)	39.4 (18 to 61)	42.2 (18 to 64)
Gender [units: participants]					
Female	25	28	78	86	217
Male	4	3	42	25	74

Outcome Measures

Hide All Outcome Measures

1. Primary: Time From Start of Administration of Investigational Medicinal Product (IMP) to Recovery of the T4/T1 Ratio to 0.9. [Time Frame: start of administration of sugammadex/neostigmine to recovery from neuromuscular blockade]

Measure Type	Primary
Measure Title	Time From Start of Administration of Investigational Medicinal Product (IMP) to Recovery of the T4/T1 Ratio to 0.9.
Measure Description	Neuromuscular functioning was monitored by applying repetitive train of four (TOF) electrical stimulations to the ulnar nerve every 15 seconds and assessing twitch response at the adductor pollicis muscle. Nerve stimulation was to continue until the ratio of the magnitude of the fourth twitch (T4) to first twitch (T1) reached >= 0.9. The greater the T4/T1 ratio the greater the recovery from neuromuscular blockade, with a value of 1.0 representing full recovery. The primary analysis was the comparison between sugammadex & neostigmine among Chinese subjects; other comparisons were secondary.
Time Frame	start of administration of sugammadex/neostigmine to recovery from neuromuscular blockade
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set (FAS) population included all subjects who received randomized treatment and had at least one efficacy measurement. In the event of missing data, imputed data were used for analysis. 291 subjects received IMP, of whom two had no efficacy measurements at all. Hence the FAS consisted of 289 subjects.

Reporting Groups

	Description
Sugammadex in Caucasian Subjects	At reappearance of T2 after the last dose of rocuronium, 2.0 mg.kg-1 sugammadex was administered.
Neostigmine in Caucasian Subjects	At reappearance of T2 after the last dose of rocuronium, 50 µg.kg-1 neostigmine (combined with 10-20 µg.kg-1 atropine, in a ratio ranging from 2.5:1 to 5:1) was administered.
Sugammadex in Chinese Subjects	At reappearance of T2 after the last dose of rocuronium, 2.0 mg.kg-1 sugammadex was administered.
Neostigmine in Chinese Subjects	At reappearance of T2 after the last dose of rocuronium, 50 µg.kg-1 neostigmine (combined with 10-20 µg.kg-1 atropine, in a ratio ranging from 2.5:1 to 5:1) was administered.

Measured Values

	Sugammadex in Caucasian Subjects	Neostigmine in Caucasian Subjects	Sugammadex in Chinese Subjects	Neostigmine in Chinese Subjects
Number of Participants Analyzed [units: participants]	**29**	**30**	**119**	**111**
Time From Start of Administration of Investigational Medicinal Product (IMP) to Recovery of the T4/T1 Ratio to 0.9. [units: minutes] Geometric Mean (95% Confidence Interval)	**1.4 (1.3 to 1.5)**	**6.7 (5.5 to 8.0)**	**1.6 (1.5 to 1.7)**	**9.1 (8.0 to 10.3)**

Statistical Analysis 1 for Time From Start of Administration of Investigational Medicinal Product (IMP) to Recovery of the T4/T1 Ratio to 0.9.

Groups [1]	Sugammadex in Chinese Subjects vs. Neostigmine in Chinese Subjects
Method [2]	ANOVA
ratio of geometric mean time to recovery [3]	5.7
95% Confidence Interval	4.9 to 6.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	The primary analysis was the comparison of the two treatments among Chinese subjects.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	ANOVA, adjusted for center effects, on log transformed times from start of administration of IMP to recovery of the T4/T1 ratio to 0.9.
[3]	Other relevant estimation information:
	Ratio of time to recovery of 0.9 T4/T1 ratio (neostigmine time / sugammadex time).

Statistical Analysis 2 for Time From Start of Administration of Investigational Medicinal Product (IMP) to Recovery of the T4/T1 Ratio to 0.9.

Groups [1]	Sugammadex in Caucasian Subjects vs. Neostigmine in Caucasian Subjects
Method [2]	ANOVA
ratio of geometric mean time to recovery [3]	4.8
97.5% Confidence Interval	3.7 to 6.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	A key secondary analysis was the comparison of the two treatments among Caucasian subjects.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	ANOVA, adjusted for center effects, on log transformed times from start of administration of IMP to recovery of the T4/T1 ratio to 0.9.
[3]	Other relevant estimation information:
	Ratio of time to recovery of 0.9 T4/T1 ratio (neostigmine time / sugammadex time).

Statistical Analysis 3 for Time From Start of Administration of Investigational Medicinal Product (IMP) to Recovery of the T4/T1 Ratio to 0.9.

Groups [1]	Sugammadex in Caucasian Subjects vs. Sugammadex in Chinese Subjects
Non-Inferiority/Equivalence Test [2]	Yes

median difference (seconds) [3]	7
97.5% Confidence Interval	-5 to 21

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	A key secondary analysis was the comparison for equivalence between Chinese subjects and Caucasian subjects.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	Equivalence was considered if the 97.5% confidence interval (CI) for median difference in recovery time (T4/T1 ratio to 0.9) was within the pre-specified range of -60 to +60 seconds.
[3]	Other relevant estimation information:
	Estimated median difference (Chinese - Caucasian) in seconds for the time to recovery of the T4/T1 ratio to 0.9 (after sugammadex).

2. Secondary: Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.7 and 0.8. [Time Frame: start of administration of sugammadex/neostigmine to recovery from neuromuscular blockade]

Measure Type	Secondary
Measure Title	Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.7 and 0.8.
Measure Description	Neuromuscular functioning was monitored by applying repetitive TOF electrical stimulations to the ulnar nerve every 15 seconds and assessing twitch response at the adductor pollicis muscle. The greater the T4/T1 ratio the greater the recovery from neuromuscular blockade.
Time Frame	start of administration of sugammadex/neostigmine to recovery from neuromuscular blockade
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The Full Analysis Set population included all subjects who received randomized treatment and had at least one efficacy measurement. In the event of missing data, imputed data were used for analysis.

Reporting Groups

	Description
Sugammadex in Caucasian Subjects	At reappearance of T2 after the last dose of rocuronium, 2.0 mg.kg-1 sugammadex was administered.
Neostigmine in Caucasian Subjects	At reappearance of T2 after the last dose of rocuronium, 50 µg.kg-1 neostigmine (combined with 10-20 µg.kg-1 atropine, in a ratio ranging from 2.5:1 to 5:1) was administered.
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Measured Values

	Sugammadex in Caucasian Subjects	**Neostigmine in Caucasian Subjects**	**Sugammadex in Chinese Subjects**	**Neostigmine in Chinese Subjects**
Number of Participants Analyzed [units: participants]	**29**	**30**	**119**	**111**
Time From Start of Administration of IMP to				

Recovery of the T4/T1 Ratio to 0.7 and 0.8. [units: minutes] Geometric Mean (95% Confidence Interval)				
Recovery of T4/T1 ratio to 0.7	1.0 (0.9 to 1.1)	3.4 (3.0 to 3.8)	1.1 (1.1 to 1.2)	4.4 (4.0 to 4.9)
Recovery of T4/T1 ratio to 0.8	1.2 (1.1 to 1.3)	4.6 (4.0 to 5.4)	1.3 (1.2 to 1.4)	6.0 (5.4 to 6.7)

No statistical analysis provided for Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.7 and 0.8.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Sugammadex in Caucasian Subjects	At reappearance of T2 after the last dose of rocuronium, 2.0 mg.kg-1 sugammadex was administered.
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Serious Adverse Events

	Sugammadex in Caucasian Subjects	Neostigmine in Caucasian Subjects	Sugammadex in Chinese Subjects	Neostigmine in Chinese Subjects
Total, serious adverse events				
# participants affected / at risk	**0/29 (0.00%)**	**2/31 (6.45%)**	**0/120 (0.00%)**	**1/111 (0.90%)**
Infections and infestations				
Enterococcal bacteraemia [1]				
# participants affected / at risk	**0/29 (0.00%)**	**1/31 (3.23%)**	**0/120 (0.00%)**	**0/111 (0.00%)**
# events	**0**	**1**	**0**	**0**
Injury, poisoning and procedural complications				
Anastomotic leak [1]				
# participants affected / at risk	**0/29 (0.00%)**	**1/31 (3.23%)**	**0/120 (0.00%)**	**0/111 (0.00%)**
# events	**0**	**1**	**0**	**0**
Incision site haemorrhage [1]				

# participants affected / at risk	0/29 (0.00%)	0/31 (0.00%)	0/120 (0.00%)	1/111 (0.90%)
# events	0	0	0	1

1 Term from vocabulary, MedDRA 13.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Sugammadex in Caucasian Subjects	At reappearance of T2 after the last dose of rocuronium, 2.0 mg.kg-1 sugammadex was administered.
Neostigmine in Caucasian Subjects	At reappearance of T2 after the last dose of rocuronium, 50 µg.kg-1 neostigmine (combined with 10-20 µg.kg-1 atropine, in a ratio ranging from 2.5:1 to 5:1) was administered.
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Other Adverse Events

	Sugammadex in Caucasian Subjects	Neostigmine in Caucasian Subjects	Sugammadex in Chinese Subjects	Neostigmine in Chinese Subjects
Total, other (not including serious) adverse events				
# participants affected / at risk	**18/29 (62.07%)**	**26/31 (83.87%)**	**73/120 (60.83%)**	**84/111 (75.68%)**
Gastrointestinal disorders				
Abdominal pain [1]				
# participants affected / at risk	**1/29 (3.45%)**	**1/31 (3.23%)**	**1/120 (0.83%)**	**6/111 (5.41%)**
# events	**2**	**1**	**1**	**6**
Abdominal pain upper [1]				
# participants affected / at risk	**0/29 (0.00%)**	**2/31 (6.45%)**	**6/120 (5.00%)**	**2/111 (1.80%)**
# events	**0**	**2**	**6**	**2**
Nausea [1]				
# participants affected / at risk	**4/29 (13.79%)**	**7/31 (22.58%)**	**10/120 (8.33%)**	**13/111 (11.71%)**
# events	**4**	**9**	**11**	**13**
[1]				

Vomiting				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**11/120 (9.17%)**	**11/111 (9.91%)**
# events	**0**	**0**	**11**	**11**
General disorders				
Fatigue [1]				
# participants affected / at risk	**2/29 (6.90%)**	**0/31 (0.00%)**	**0/120 (0.00%)**	**0/111 (0.00%)**
# events	**2**	**0**	**0**	**0**
Pyrexia [1]				
# participants affected / at risk	**2/29 (6.90%)**	**1/31 (3.23%)**	**16/120 (13.33%)**	**16/111 (14.41%)**
# events	**2**	**1**	**17**	**16**
Sensation of foreign body [1]				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**8/120 (6.67%)**	**4/111 (3.60%)**
# events	**0**	**0**	**8**	**4**
Injury, poisoning and procedural complications				
Anaesthetic complication cardiac [1]				
# participants affected / at risk	**0/29 (0.00%)**	**5/31 (16.13%)**	**1/120 (0.83%)**	**7/111 (6.31%)**
# events	**0**	**5**	**2**	**7**
Incision site pain [1]				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**28/120 (23.33%)**	**26/111 (23.42%)**
# events	**0**	**0**	**28**	**26**
Procedural hypotension [1]				
# participants affected / at risk	**6/29 (20.69%)**	**14/31 (45.16%)**	**1/120 (0.83%)**	**0/111 (0.00%)**
# events	**8**	**20**	**1**	**0**
Procedural nausea [1]				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**4/120 (3.33%)**	**7/111 (6.31%)**
# events	**0**	**0**	**4**	**7**
Procedural pain [1]				
# participants affected / at risk	**13/29 (44.83%)**	**12/31 (38.71%)**	**10/120 (8.33%)**	**10/111 (9.01%)**
# events	**20**	**15**	**10**	**10**
Procedural vomiting [1]				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**4/120 (3.33%)**	**7/111 (6.31%)**
# events	**0**	**0**	**4**	**7**
Wound complication [1]				
# participants affected / at risk	**3/29 (10.34%)**	**3/31 (9.68%)**	**3/120 (2.50%)**	**2/111 (1.80%)**
# events	**3**	**4**	**3**	**2**
Nervous system disorders				

Dizziness [1]				
# participants affected / at risk	**2/29 (6.90%)**	**0/31 (0.00%)**	**11/120 (9.17%)**	**22/111 (19.82%)**
# events	**2**	**0**	**11**	**23**
Headache [1]				
# participants affected / at risk	**1/29 (3.45%)**	**2/31 (6.45%)**	**5/120 (4.17%)**	**6/111 (5.41%)**
# events	**1**	**2**	**5**	**6**
Psychiatric disorders				
Insomnia [1]				
# participants affected / at risk	**2/29 (6.90%)**	**3/31 (9.68%)**	**2/120 (1.67%)**	**1/111 (0.90%)**
# events	**2**	**3**	**2**	**1**
Reproductive system and breast disorders				
Vaginal haemorrhage [1]				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**5/120 (4.17%)**	**9/111 (8.11%)**
# events	**0**	**0**	**5**	**9**
Respiratory, thoracic and mediastinal disorders				
Increased upper airway secretion [1]				
# participants affected / at risk	**0/29 (0.00%)**	**0/31 (0.00%)**	**5/120 (4.17%)**	**10/111 (9.01%)**
# events	**0**	**0**	**5**	**10**
Surgical and medical procedures				
Hypotensive anaesthesia procedure [1]				
# participants affected / at risk	**1/29 (3.45%)**	**2/31 (6.45%)**	**0/120 (0.00%)**	**0/111 (0.00%)**
# events	**1**	**2**	**0**	**0**

1 Term from vocabulary, MedDRA 13.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

☑ **Restriction Description:** The PI must not publish/publicly present any interim results without prior written consent of sponsor. The PI must provide copies of material for sponsor to review, 45 days prior to submission for publication/presentation. The sponsor may review/comment. If the parties disagree on the appropriateness of the data analysis and presentation, the PI must agree to meet prior to submission for publication/presentation to make good faith efforts to discuss and resolve any issues or disagreement.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp.
e-mail: ClinicalTrialsDisclosure@merck.com

Publications of Results:

Wu X, Oerding H, Liu J, Vanacker B, Yao S, Dahl V, Xiong L, Claudius C, Yue Y, Huang Y, Abels E, Rietbergen H, Woo T. Rocuronium blockade reversal with sugammadex vs. neostigmine: randomized study in Chinese and Caucasian subjects. BMC Anesthesiol. 2014 Jul 12;14:53. doi: 10.1186/1471-2253-14-53. eCollection 2014.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00825812 History of Changes
Other Study ID Numbers:	P05768 19.4.324
Study First Received:	January 15, 2009
Results First Received:	July 22, 2011
Last Updated:	October 30, 2015
Health Authority:	Denmark: Danish Medicines Agency China: Food and Drug Administration

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