Comparison of Sugammadex With Neostigmine During Laparoscopic Cholecystectomy or Appendectomy (P05699)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00724932

First received: July 28, 2008
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History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

The current trial was designed to demonstrate faster recovery from a neuromuscular blockade (NMB) induced by rocuronium after reversal at 1-2 Post Tetanic Count (PTC) by 4.0 mg.kg-1 sugammadex compared to 50 µg.kg-1 neostigmine at reappearance of second twitch (T2) in participants undergoing laparoscopic cholecystectomy or appendectomy under propofol anesthesia, to compare safety and to evaluate operating room and Post Anesthetic Care Unit (PACU) length of stay.

Condition	Intervention	Phase
Anesthesia, General	Drug: Rocuronium Drug: Sugammadex Drug: Neostigmine Drug: Atropine	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Multi-center, Randomized, Parallel-group, Comparative, Active-controlled, Safety-assessor Blinded Trial in Adult Subjects Comparing the Efficacy and Safety of Sugammadex (SCH 900616, ORG 25969) Administered at 1-2 PTC With Neostigmine Administered at Reappearance of T2 in Subjects Undergoing Laparoscopic Cholecystectomy or Appendectomy 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, Sugammadex or Neostigmine) to Recovery of the Fourth Twitch/First Twitch (T4/T1) Ratio to 0.9 [Time Frame: From start of IMP administration to recovery of T4/T1 ratio to 0.9 (ranging from ~2 minutes to ~9 minutes)] [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 & assessing twitch response at the adductor pollicis muscle. T1 and T4 refer to the magnitudes (heights) of the first and fourth twitches, respectively, after TOF nerve stimulation. The T4/T1 Ratio (expressed as a decimal of up to 1.0) indicates the extent of recovery from neuromuscular blockade (NMB). In this study, twitch responses were recorded until the T4/T1 Ratio reached >= 0.9, the minimum acceptable ratio that indicated recovery from NMB. A faster time to recovery of the T4/T1 Ratio to 0.9 indicates a faster recovery from NMB.

Secondary Outcome Measures:

- Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.7 [Time Frame: From start of IMP administration to recovery of T4/T1 Ratio to 0.7 (ranging from ~2 minutes to ~5 minutes)] [Designated as safety issue: No]

  Neuromuscular functioning was monitored by applying repetitive TOF electrical stimulations to the ulnar nerve every 15 seconds & assessing twitch response at the adductor pollicis muscle. T1 and T4 refer to the magnitudes (heights) of the first and fourth twitches, respectively, after TOF nerve stimulation. The T4/T1 Ratio (expressed as a decimal of up to 1.0). A faster time to recovery of the T4/T1 Ratio to 0.7 indicates a faster recovery from NMB.

- Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.8 [Time Frame: From start of IMP administration to recovery of T4/T1 Ratio to 0.8 (ranging from ~2 minutes to ~6 minutes)] [Designated as safety issue: No]

  Neuromuscular functioning was monitored by applying repetitive TOF electrical stimulations to the ulnar nerve every 15 seconds & assessing twitch response at the adductor pollicis muscle. T1 and T4 refer to the magnitudes (heights) of the first and fourth twitches, respectively, after TOF nerve stimulation. The T4/T1 Ratio (expressed as a decimal of up to 1.0). A faster time to recovery of the T4/T1 Ratio to 0.8 indicates a faster recovery from NMB.

- Number of Participants Who Experienced Pre-treatment Serious Adverse Events (SAEs) and Post-treatment SAEs [Time Frame: From signing of informed consent to end of trial (7 days after surgery)] [Designated as safety issue: Yes]

  An SAE is defined as any untoward medical occurrence that at any dose: results in death; is life-threatening; requires in-patient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/incapacity; or is a congenital anomaly/birth defect. Participants were monitored for occurrence SAEs for up to 7 days after last dose IMP. Pre-treatment refers to the period from signing of the informed consent up to start of IMP administration. Post-treatment refers to the period from start of IMP administration to 7 days after IMP administration.

- Number of Participants Who Experienced Pre-treatment Non-serious Adverse Events (AEs) and Post-treatment Non-serious AEs [Time Frame: From signing of informed consent to end of trial (7 days after surgery)] [Designated as safety issue: Yes]

  An AE is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body, whether or not considered related to the use of the product. Participants were monitored for occurrence AEs for up to 7 days after last dose IMP. Pre-treatment refers to the period from signing of the informed consent up to start of IMP administration. Post-treatment refers to the period from start of IMP administration to 7 days after IMP administration.

Other Outcome Measures:

- Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.5 and 0.6 [Time Frame: From start of IMP administration to recovery of T4/T1 Ratio to 0.5 and 0.6 (ranging from ~1 minute to ~4 minutes)] [Designated as safety issue: No]

  Neuromuscular functioning was monitored by applying repetitive TOF electrical stimulations to the ulnar nerve every 15 seconds & assessing twitch response at the adductor pollicis muscle. T1 and T4 refer to the magnitudes (heights) of the first and fourth twitches, respectively, after TOF nerve stimulation. The T4/T1 Ratio (expressed as a decimal of up to 1.0). Faster times to recovery of the T4/T1 Ratios to 0.5 and 0.6 indicate faster recoveries from NMB.

- Time From Start of Administration of the Last Dose of Rocuronium to Recovery of the T4/T1 Ratio to 0.5, 0.6, 0.7, 0.8 and 0.9 [Time Frame: From start of last dose of rocuronium to recovery of T4/T1 Ratio to 0.5, 0.6, 0.7, 0.8 and 0.9 (ranging from ~12 minutes to ~36

minutes)] [Designated as safety issue: No]

Neuromuscular functioning was monitored by applying repetitive TOF electrical stimulations to the ulnar nerve every 15 seconds & assessing twitch response at the adductor pollicis muscle. T1 and T4 refer to the magnitudes (heights) of the first and fourth twitches, respectively, after TOF nerve stimulation. The T4/T1 Ratio (expressed as a decimal of up to 1.0). A faster time to recovery of the T4/T1 Ratio indicates a faster recovery from NMB.

- Time From Start of Administration of the Last Dose of Rocuronium to the Time of 1-2 PTC in the 4.0 mg.Kg-1 Sugammadex Group [Time Frame: From last dose of rocuronium to 1-2 PTC (up to ~9 minutes)] [Designated as safety issue: No]

  The time of 1-2 PTC refers to when 1-2 twitches are generated after tetanic stimulation. Time to 1-2 PTC is the time point of the last single twitch >0 or baseline (in case of noise or direct stimulation) within the sequence of a PTC measurement. 1-2 PTC was the target depth of NMB at which sugammadex was to be administered.

- Time From Start of Administration of the Last Dose of Rocuronium to the Time of Reappearance of T2 in the 50 µg.Kg-1 Neostigmine Group [Time Frame: From last dose of rocuronium to reappearance of T2 (up to ~26 minutes)] [Designated as safety issue: No]

  The time of reappearance of T2 refers to when the second twitch reappears after TOF stimulation. Reappearance of T2 was the target depth of NMB at which neostigmine was to be administered.

- Mean Systolic Blood Pressure [Time Frame: At screening, pre-rocuronium, pre-IMP, at 2, 5, 10, and 30 minutes post-IMP, and at the post-anesthetic visit (the day after surgery)] [Designated as safety issue: Yes]

  Systolic Blood Pressure was measured at screening, before start of rocuronium administration, before start of IMP administration, at 2, 5, 10, 30 minutes post-IMP administration, and at the post-anesthetic visit (the day after surgery).

- Mean Diastolic Blood Pressure [Time Frame: At screening, pre-rocuronium, pre-IMP, at 2, 5, 10, and 30 minutes post-IMP, and at the post-anesthetic visit (the day after surgery)] [Designated as safety issue: Yes]

  Diastolic Blood Pressure was measured at screening, before start of rocuronium administration, before start of IMP administration, at 2, 5, 10, 30 minutes post-IMP administration, and at the post-anesthetic visit (the day after surgery).

- Mean Heart Rate [Time Frame: At screening, pre-rocuronium, pre-IMP, at 2, 5, 10, and 30 minutes post-IMP, and at the post-anesthetic visit (the day after surgery)] [Designated as safety issue: Yes]

  Heart Rate was measured at screening, before start of rocuronium administration, before start of IMP administration, at 2, 5, 10, 30 minutes post-IMP administration, and at the post-anesthetic visit (the day after surgery).

- Number of Participants Who Had Physical Examinations [Time Frame: At screening (within 7 days prior to surgery) and at the post-anesthetic visit (the day after surgery)] [Designated as safety issue: Yes]

  Physical examinations were to be conducted at screening (within 7 days prior to surgery) and at the post-anesthetic visit (the day after surgery).

- Number of Participants With Train-of-Four- (TOF-) Watch® SX and Arm Board Related Adverse Events [Time Frame: From induction of anesthesia to recovery from NMB (up to ~3 hours)] [Designated as safety issue: Yes]

  Events were to be collected for the entire period of neuromuscular transmission monitoring and were defined as an occurrence that resulted or could have resulted in: death; a serious deterioration in the state of health of a user; an occurrence which might, if it recurred, lead to death or serious deterioration in health; inaccuracy as well as any inadequacy in the labeling or instructions which could cause misuse or incorrect maintenance or adjustment which might lead to a death or serious deterioration in health; an examination of the medical device or the information supplied with the medical device indicated some factor with the potential for an incident involving death or serious deterioration in health; malfunction or deterioration in characteristics and/or performance of a medical device, which might lead to death, or serious deterioration in health; technical/medical recalls involving risk of death or serious deterioration in the state of health of the user.

- Number of Participants With Reoccurrence of Neuromuscular Blockade Based on the Train-of-Four- (TOF-) Watch® SX Recording (i.e. a Decline in T4/T1 Ratio From >=0.9 to <0.8 in at Least Three Consecutive TOF Values) [Time Frame: Up to 30 minutes after IMP administration] [Designated as safety issue: Yes]

  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. T1 and T4 refer to the magnitudes (heights) of the 1st and 4th twitches, respectively, after TOF stimulation. The T4/T1 Ratio is expressed as a decimal of up to 1.0. A higher ratio indicates greater recovery from NMB. A decline in the T4/T1 ratio from >=0.9 (indicating a recovery from NMB) to <0.8 for at least three consecutive TOF values was considered to be a reoccurrence of NMB.

- Number of Participants With Clinical Evidence of Reoccurrence of Neuromuscular Blockade or Residual Neuromuscular Blockade (Routine Oxygen Saturation by Pulse Oximetry and Breath Frequency Measurement) [Time Frame: Up to 24 hours after IMP administration]

[Designated as safety issue: Yes]

Clinical evidence of reoccurrence of NMB or residual NMB was assessed by oxygen saturation (by pulse oximetry) and breath frequency measurements as per routine practice after anesthesia and neuromuscular monitoring.

- Number of Participants With Events Due to a Possible Interaction of Sugammadex With Endogenous Compounds or With Exogenous Compounds Other Than Rocuronium [Time Frame: Up to 7 days after IMP administration] [Designated as safety issue: Yes]

  Any evidence of events due to a possible interaction of sugammadex with endogenous compounds or with exogenous compounds other than rocuronium, was to be recorded.

- Monitoring of Clinical Signs of Recovery According to Routine Anesthetic Procedures at the Trial Sites [Time Frame: Up to PACU discharge (up to ~4.5 hours)] [Designated as safety issue: Yes]

  The monitoring of clinical signs of recovery was to be conducted based on the routine anesthetic procedures at each site.

- Number of Female Participants or Partners of Male Participants Who Became Pregnant During Study [Time Frame: Up to 30 days after IMP administration] [Designated as safety issue: Yes]

  Thirty days after administration of IMP, female participants of childbearing potential were asked whether they became pregnant during the trial and male participants were asked whether their partner (if of childbearing potential) became pregnant during the trial.

- Time From Operating Room Admission to Operating Room Discharge Ready [Time Frame: From Operating Room admission to Operating Room discharge ready (up to ~3 hours)] [Designated as safety issue: No]

  The time of Operating Room admission was defined as the time at which the participant was physically placed into the Operating Room. The time of Operating Room discharge ready was defined as time at which the participant had T4/T1 ratio of ≥0.9 and the participant's wound dressing was in place.

- Time From Operating Room Admission to Actual Operating Room Discharge [Time Frame: From Operating Room admission to actual Operating Room discharge (up to ~3 hours)] [Designated as safety issue: No]

  The time of Operating Room admission was defined as the time at which the participant was physically placed into the Operating Room. The time of Operating Room discharge was defined as the actual time the participant was discharged from the Operating Room.

- Time From Operating Room Discharge Ready to Actual Operating Room Discharge [Time Frame: From Operating Room discharge ready to actual Operating Room discharge (up to ~5 minutes)] [Designated as safety issue: No]

  The time of Operating Room discharge ready was defined as time at which the participant had T4/T1 ratio of >=0.9 and the participant's wound dressing was in place. The time of Operating Room discharge was defined as the actual time the participant was discharged from the Operating Room.

- Time From Start of IMP Administration to T4/T1 Ratio of <=0.60, >0.60 - <=0.70, >0.70 - <=0.80, >0.80 - <0.90 and >=0.90 [Time Frame: From start of IMP administration to recovery of the T4/T1 ratio to the designated value (ranging from ~1 minute to ~10 minutes)] [Designated as safety issue: No]

  The time of IMP administration was defined as the actual time at which IMP administration was started.

- Time From Start of IMP Administration to Tracheal Extubation [Time Frame: From start of IMP administration to tracheal extubation (up to ~21 minutes)] [Designated as safety issue: No]

  The time of IMP administration was defined as the actual time at which IMP administration was started. The time of tracheal extubation was defined as the actual time at which the participant was extubated.

- Time From Start of IMP Administration to Operating Room Discharge Ready [Time Frame: From start of IMP administration to Operating Room discharge ready (up to ~21 minutes)] [Designated as safety issue: No]

  The time of IMP administration was defined as the actual time at which IMP administration was started. The time of Operating Room discharge ready was defined as time at which the participant had T4/T1 ratio of >=0.9 and the participant's wound dressing was in place.

- Time From Start of IMP Administration to Actual Operating Room Discharge [Time Frame: From start of IMP administration to actual Operating Room discharge (up to ~26 minutes)] [Designated as safety issue: No]

  The time of IMP administration was defined as the actual time at which IMP administration was started. The time of Operating Room discharge was defined as the actual time at which the participant was discharged from the Operating Room.

- Time From Tracheal Extubation to Operating Room Discharge Ready [Time Frame: From tracheal extubation to Operating Room discharge

ready (up to ~1 minute)] [Designated as safety issue: No]

The time of tracheal extubation was defined as the actual time at which the participant was extubated. The time of Operating Room discharge ready was defined as time at which the participant had T4/T1 ratio of >=0.9 and the participant's wound dressing was in place.

- Time From Tracheal Extubation to Actual Operating Room Discharge [Time Frame: From tracheal extubation to actual OR discharge (up to ~5 minutes)] [Designated as safety issue: No]

  The time of tracheal extubation was defined as the actual time at which the participant was extubated. The time of Operating Room discharge was defined as the actual time at which the participant was discharged from the Operating Room.

- Time From Operating Room Discharge Ready to Post Anesthetic Care Unit (PACU) Discharge Ready [Time Frame: From Operating Room discharge ready to PACU discharge ready (up to ~33 minutes)] [Designated as safety issue: No]

  The time of Operating Room discharge ready was defined as time at which the participant had T4/T1 ratio of >=0.9 and the participant's wound dressing was in place. The time of PACU discharge ready was defined as the time at which the participant had a Modified Aldrete Score >=9. The Modified Aldrete Score was to be assessed at PACU arrival, at 5, 15, 30, 45, 60 minutes after PACU arrival and every 15 minutes thereafter (if applicable) until the participant was ready to be discharged from the PACU. The Modified Aldrete Postoperative Recovery Score (range = 0-10) is calculated based on scores of 0 to 2 each for Activity, Respiration, Circulation, Consciousness and Oxygen Saturation, with a higher score indicating increased postoperative recovery.

- Time From Operating Room Discharge Ready to Actual PACU Discharge [Time Frame: From Operating Room discharge ready to actual PACU discharge (up to ~4.5 hours)] [Designated as safety issue: No]

  The time of Operating Room discharge ready was defined as time at which the participant had T4/T1 ratio of >=0.9 and the participant's wound dressing was in place. The time of PACU discharge was defined as the actual time the participant was discharged from the PACU.

- Time From Actual Operating Room Discharge to PACU Discharge Ready [Time Frame: From actual Operating Room discharge to PACU discharge ready (up to ~30 minutes)] [Designated as safety issue: No]

  The time of Operating Room discharge was defined as the actual time the participant was discharged from the Operating Room. The time of PACU discharge ready was defined as the time at which the participant had a Modified Aldrete Score >=9. The Modified Aldrete Score was to be assessed at PACU arrival, at 5, 15, 30, 45, 60 minutes after PACU arrival and every 15 minutes thereafter (if applicable) until the participant was ready to be discharged from the PACU. The Modified Aldrete Postoperative Recovery Score (range = 0-10) is calculated based on scores of 0 to 2 each for Activity, Respiration, Circulation, Consciousness and Oxygen Saturation, with a higher score indicating increased postoperative recovery.

- Time From Actual Operating Room Discharge to Actual PACU Discharge [Time Frame: From actual Operating Room discharge to actual PACU discharge (up to ~4.4 hours)] [Designated as safety issue: No]

  The time of Operating Room discharge was defined as the actual time the participant was discharged from the Operating Room. The time of PACU discharge was defined as the actual time the participant was discharged from the PACU.

- Time From PACU Admit to PACU Discharge Ready [Time Frame: From PACU admit to PACU discharge ready (up to ~25 minutes)] [Designated as safety issue: No]

  The time of PACU admit was defined as the actual time the participant was admitted to the PACU. The time of PACU discharge ready was defined as the time at which the participant had a Modified Aldrete Score >=9. The Modified Aldrete Score was to be assessed at PACU arrival, at 5, 15, 30, 45, 60 minutes after PACU arrival and every 15 minutes thereafter (if applicable) until the participant was ready to be discharged from the PACU. The Modified Aldrete Postoperative Recovery Score (range = 0-10) is calculated based on scores of 0 to 2 each for Activity, Respiration, Circulation, Consciousness and Oxygen Saturation, with a higher score indicating increased postoperative recovery.

- Time From PACU Admit to Actual PACU Discharge [Time Frame: From PACU admit to actual PACU discharge (up to ~4.3 hours)] [Designated as safety issue: No]

  The time of PACU admit was defined as the actual time the participant was admitted to the PACU. The time of PACU discharge was defined as the actual time the participant was discharged from the PACU.

Enrollment:	140
Study Start Date:	July 2008
Study Completion Date:	May 2009
Primary Completion Date:	April 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions

Experimental: Sugammadex 4.0 mg.kg-1 sugammadex at 1-2 PTC	Drug: Rocuronium Participants will receive an intravenous (i.v.) single bolus dose of 0.6 mg.kg-1 rocuronium. After this dose, maintenance doses of 0.1-0.2 mg.kg-1 rocuronium may be given. Other Names: • rocuronium bromide • Esmeron® Drug: Sugammadex After the last dose of rocuronium has been administered, participants will receive, according to the randomization, a single bolus dose of 4.0 mg.kg-1 sugammadex at 1-2 PTC. Other Names: • Org 25969 • SCH 900616 • MK-8616 • Bridion®
Experimental: Neostigmine 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2	Drug: Rocuronium Participants will receive an intravenous (i.v.) single bolus dose of 0.6 mg.kg-1 rocuronium. After this dose, maintenance doses of 0.1-0.2 mg.kg-1 rocuronium may be given. Other Names: • rocuronium bromide • Esmeron® Drug: Neostigmine After the last dose of rocuronium has been administered, participants will receive, according to the randomization, 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2. Other Name: Prostigmin® Drug: Atropine After the last dose of rocuronium has been administered, participants will receive, according to randomization, 10 µg.kg-1 atropine (with neostigmine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2. Other Name: atropine sulfate

Detailed Description:

In those surgical procedures where a neuromuscular block is desired for intubation and/or avoid unwanted muscular activity, anesthesiologists may use a more profound NMB until the end of surgery, e.g. in open abdominal procedures or during laparoscopic procedures in order to improve surgical conditions. Reversal with sugammadex at a dose of 4.0 mg.kg-1 at 1-2 PTC after an intubation dose of 0.6 mg.kg-1 or maintenance dosing rocuronium has been found to be both safe and efficacious in previous clinical trials but has never been investigated exclusively in participants undergoing laparoscopic cholecystectomy or appendectomy.

With sugammadex profound muscle relaxation may now be provided right up to the end of the surgical procedure. This may lead to improved Patient Outcomes, such as improvement in the time from end of surgery to the discharge to the PACU. In this multi-center, randomized, parallel-group, active-controlled, safety-assessor blinded trial such benefits will be further investigated.

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Participants of American Society of Anesthesiologists class 1-3
- Participants of age above or equal to the age of 18 years
- Participants who are scheduled to undergo a laparoscopic cholecystectomy or appendectomy under general anesthesia requiring neuromuscular relaxation with rocuronium, and if applicable, maintenance of neuromuscular blockade
- Participants who have given written informed consent

Exclusion Criteria:

- Participants in whom a difficult intubation because of anatomical malformations is expected
- Participants known or suspected to have neuromuscular disorders affecting NMB
- Participants known or suspected to have a significant renal dysfunction
- Participants known or suspected to have a severe hepatic dysfunction
- Participants known or suspected to have (family) history of malignant hyperthermia
- Participants known or suspected to have an allergy to opioids, muscle relaxants or other medication used during general anesthesia
- Participants in whom the use of neostigmine and/or atropine is contraindicated
- Female participants who are pregnant (pregnancy will be excluded for women both from medical history and by a human chorionic gonadotropin (hCG) test within 24h before surgery, except for women who are not of childbearing potential, i.e. at least 2 years menopausal or have undergone tubal ligation or a hysterectomy)
- Female participants who are breast-feeding
- Participants who participated in another clinical trial not pre-approved by the sponsor, within 30 days of entering into trial 19.4.318 (P05699)
- Participants who have already participated in a sugammadex trial

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:

Geldner G, Niskanen M, Laurila P, Mizikov V, Hübler M, Beck G, Rietbergen H, Nicolayenko E. A randomised controlled trial comparing sugammadex and neostigmine at different depths of neuromuscular blockade in patients undergoing laparoscopic surgery. Anaesthesia. 2012 Sep;67(9):991-8. doi: 10.1111/j.1365-2044.2012.07197.x. Epub 2012 Jun 14.

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Responsible Party:	Merck Sharp & Dohme Corp.
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Results First Received:	March 14, 2013
Last Updated:	February 26, 2015
Health Authority:	Finland: Finnish Medicines Agency Germany: Federal Institute for Drugs and Medical Devices Russia: Ministry of Health of the Russian Federation United Kingdom: Medicines and Healthcare Products Regulatory Agency

Additional relevant MeSH terms:

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

ClinicalTrials.gov processed this record on April 10, 2016

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Comparison of Sugammadex With Neostigmine During Laparoscopic Cholecystectomy or Appendectomy (P05699)

This study has been completed.

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Information provided by (Responsible Party):
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ClinicalTrials.gov Identifier:
NCT00724932

First received: July 28, 2008
Last updated: February 26, 2015
Last verified: February 2015
History of Changes

Results First Received: March 14, 2013

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Outcomes Assessor); Primary Purpose: Treatment
Condition:	Anesthesia, General
Interventions:	Drug: Rocuronium Drug: Sugammadex Drug: Neostigmine Drug: Atropine

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
Participants were recruited from 10 sites in Germany, Russia, Finland and the United Kingdom between July 2008 and March 2009.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 Post Tetanic Count (PTC)
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine: atropine) at reappearance of the second twitch (T2)

Participant Flow: Overall Study

	Sugammadex	Neostigmine
STARTED	**70**	**70**
COMPLETED	**65**	**67**
NOT COMPLETED	**5**	**3**
Lost to Follow-up	**1**	**0**
Not treated	**4**	**3**

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.
The Baseline Analysis Population consisted of randomized participants who received investigational medicinal product (IMP). Four participants randomized to Sugammadex did not receive IMP and three participants randomized to receive Neostigmine did not receive IMP.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2
Total	Total of all reporting groups

Baseline Measures

	Sugammadex	Neostigmine	Total
Number of Participants [units: participants]	**66**	**67**	**133**
Age [units: years] Mean (Standard Deviation)	**51 (16)**	**51 (14)**	**51 (15)**
Gender [units: participants]			
Female	**49**	**43**	**92**
Male	**17**	**24**	**41**

Outcome Measures

Hide All Outcome Measures

1. Primary: Time From Start of Administration of Investigational Medicinal Product (IMP, Sugammadex or Neostigmine) to Recovery of the Fourth Twitch/First Twitch (T4/T1) Ratio to 0.9 [Time Frame: From start of IMP administration to recovery of T4/T1 ratio to 0.9 (ranging from ~2 minutes to ~9 minutes)]

Measure Type	Primary
Measure Title	Time From Start of Administration of Investigational Medicinal Product (IMP, Sugammadex or Neostigmine) to Recovery of the Fourth Twitch/First Twitch (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 & assessing twitch response at the adductor pollicis muscle. T1 and T4 refer to the magnitudes (heights) of the first and fourth twitches, respectively, after TOF nerve stimulation. The T4/T1 Ratio (expressed as a decimal of up to 1.0) indicates the extent of recovery from neuromuscular blockade (NMB). In this study, twitch responses were recorded until the T4/T1 Ratio reached >= 0.9, the minimum acceptable ratio that indicated recovery from NMB. A faster time to recovery of the T4/T1 Ratio to 0.9 indicates a faster recovery from NMB.
Time Frame	From start of IMP administration to recovery of T4/T1 ratio to 0.9 (ranging from ~2 minutes to ~9 minutes)
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 Intent-To-Treat (ITT) Population consisted of all randomized participants who received IMP and had at least one efficacy measurement. Imputed recovery times were used in cases of missing times.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	**Neostigmine**
Number of Participants Analyzed [units: participants]	**66**	**65**
Time From Start of Administration of Investigational Medicinal Product (IMP, Sugammadex or Neostigmine) to Recovery of the Fourth Twitch/First Twitch (T4/T1) Ratio to 0.9 [units: minutes] Geometric Mean (95% Confidence Interval)	**2.4 (2.1 to 2.7)**	**8.4 (7.2 to 9.8)**

Statistical Analysis 1 for Time From Start of Administration of Investigational Medicinal Product (IMP, Sugammadex or Neostigmine) to Recovery of the Fourth Twitch/First Twitch (T4/T1) Ratio to 0.9

Groups [1]	All groups
Method [2]	ANOVA

P Value [3]	<0.0001
Geometric Mean Ratio (Final Values) [4]	3.4
95% Confidence Interval	2.8 to 4.1

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	To evaluate the efficacy of sugammadex compared to neostigmine, the ratio of the geometric means of time to recovery of the T4/T1 ratio to 0.9 was calculated using a two-way analysis of variance (ANOVA) model adjusted for treatment group and trial site.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	Testing was performed using a two-sided test at the 0.05 significance level. There was only one primary comparison, therefore no adjustment for multiplicity was required.
[4]	Other relevant estimation information:
	Sugammadex is the numerator and neostigmine the denominator. The estimated value for the geometric mean ratio presents how many times the geometric mean time to recovery of the T4/T1 ratio to 0.9 was faster with sugammadex compared to neostigmine.

2. Secondary: Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.7 [Time Frame: From start of IMP administration to recovery of T4/T1 Ratio to 0.7 (ranging from ~2 minutes to ~5 minutes)]

Measure Type	Secondary
Measure Title	Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.7
Measure Description	Neuromuscular functioning was monitored by applying repetitive TOF electrical stimulations to the ulnar nerve every 15 seconds & assessing twitch response at the adductor pollicis muscle. T1 and T4 refer to the magnitudes (heights) of the first and fourth twitches, respectively, after TOF nerve stimulation. The T4/T1 Ratio (expressed as a decimal of up to 1.0). A faster time to recovery of the T4/T1 Ratio to 0.7 indicates a faster recovery from NMB.
Time Frame	From start of IMP administration to recovery of T4/T1 Ratio to 0.7 (ranging from ~2 minutes to ~5 minutes)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement. Imputed recovery times were used in cases of missing recovery times.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	**Neostigmine**
Number of Participants Analyzed	**66**	**65**

[units: participants]		
Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.7 **[units: minutes]** **Geometric Mean (95% Confidence Interval)**	**1.6 (1.5 to 1.8)**	**4.1 (3.7 to 4.6)**

Statistical Analysis 1 for Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.7

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	<0.0001
Geometric Mean Ratio (Final Values) [4]	2.5
95% Confidence Interval	2.1 to 2.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	To evaluate the efficacy of sugammadex compared to neostigmine, the ratio of the geometric means of time to recovery of the T4/T1 ratio to 0.7 was calculated using a two-way ANOVA model adjusted for treatment group and trial site.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The p-value is not adjusted for multiplicity.
[4]	Other relevant estimation information:
	Sugammadex is the numerator and neostigmine the denominator. The estimated value for the geometric mean ratio presents how many times the geometric mean time to recovery of the T4/T1 ratio to 0.7 was faster with sugammadex compared to neostigmine.

3. Secondary: Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.8 [Time Frame: From start of IMP administration to recovery of T4/T1 Ratio to 0.8 (ranging from ~2 minutes to ~6 minutes)]

Measure Type	Secondary
Measure Title	Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.8
Measure Description	Neuromuscular functioning was monitored by applying repetitive TOF electrical stimulations to the ulnar nerve every 15 seconds & assessing twitch response at the adductor pollicis muscle. T1 and T4 refer to the magnitudes (heights) of the first and fourth twitches, respectively, after TOF nerve stimulation. The T4/T1 Ratio (expressed as a decimal of up to 1.0). A faster time to recovery of the T4/T1 Ratio to 0.8 indicates a faster recovery from NMB.
Time Frame	From start of IMP administration to recovery of T4/T1 Ratio to 0.8 (ranging from ~2 minutes to ~6 minutes)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement. Imputed recovery times were used in cases of missing recovery times.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	Neostigmine
Number of Participants Analyzed [units: participants]	**66**	**65**
Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.8 [units: minutes] Geometric Mean (95% Confidence Interval)	**1.9 (1.7 to 2.1)**	**5.6 (4.9 to 6.3)**

Statistical Analysis 1 for Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.8

Groups [1]	All groups
Method [2]	ANOVA
P Value [3]	<0.0001
Geometric Mean Ratio (Final Values) [4]	2.9
95% Confidence Interval	2.5 to 3.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	To evaluate the efficacy of sugammadex compared to neostigmine, the ratio of the geometric means of time to recovery of the T4/T1 ratio to 0.8 was calculated using a two-way ANOVA model adjusted for treatment group and trial site.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	The p-value is not adjusted for multiplicity.
[4]	Other relevant estimation information:
	Sugammadex is the numerator and neostigmine the denominator. The estimated value for the geometric mean ratio presents how many times the geometric mean time to recovery of the T4/T1 ratio to 0.8 was faster with sugammadex compared to neostigmine.

4. Secondary: Number of Participants Who Experienced Pre-treatment Serious Adverse Events (SAEs) and Post-treatment SAEs [Time Frame: From signing of informed consent to end of trial (7 days after surgery)]

Measure Type	Secondary
Measure Title	Number of Participants Who Experienced Pre-treatment Serious Adverse Events (SAEs) and Post-treatment SAEs
Measure Description	An SAE is defined as any untoward medical occurrence that at any dose: results in death; is life-threatening; requires in-patient hospitalization or prolongation of existing hospitalization; results in persistent or significant disability/incapacity; or is a congenital anomaly/birth defect.

	Participants were monitored for occurrence SAEs for up to 7 days after last dose IMP. Pre-treatment refers to the period from signing of the informed consent up to start of IMP administration. Post-treatment refers to the period from start of IMP administration to 7 days after IMP administration.
Time Frame	From signing of informed consent to end of trial (7 days after surgery)
Safety Issue	Yes

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 All-Subjects-Treated (AST) Population consisted of all randomized participants who received IMP.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	**Neostigmine**
Number of Participants Analyzed [units: participants]	**66**	**67**
Number of Participants Who Experienced Pre-treatment Serious Adverse Events (SAEs) and Post-treatment SAEs [units: participants]		
Pre-treatment SAE	**1**	**0**
Post-treatment SAE	**4**	**6**

No statistical analysis provided for Number of Participants Who Experienced Pre-treatment Serious Adverse Events (SAEs) and Post-treatment SAEs

5. Secondary: Number of Participants Who Experienced Pre-treatment Non-serious Adverse Events (AEs) and Post-treatment Non-serious AEs [Time Frame: From signing of informed consent to end of trial (7 days after surgery)]

Measure Type	Secondary
Measure Title	Number of Participants Who Experienced Pre-treatment Non-serious Adverse Events (AEs) and Post-treatment Non-serious AEs
Measure Description	An AE is defined as any unfavorable and unintended change in the structure, function, or chemistry of the body, whether or not considered related to the use of the product. Participants were monitored for occurrence AEs for up to 7 days after last dose IMP. Pre-treatment refers to the period from signing of the informed consent up to start of IMP administration. Post-treatment refers to the period from start of IMP administration to 7 days after IMP administration.
Time Frame	From signing of informed consent to end of trial (7 days after surgery)
Safety Issue	Yes

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 AST Population consisted of all randomized participants who received IMP.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	Neostigmine
Number of Participants Analyzed [units: participants]	**66**	**67**
Number of Participants Who Experienced Pre-treatment Non-serious Adverse Events (AEs) and Post-treatment Non-serious AEs [units: participants]		
Pre-treatment non-serious AE	**38**	**34**
Post-treatment non-serious AE	**65**	**65**

No statistical analysis provided for Number of Participants Who Experienced Pre-treatment Non-serious Adverse Events (AEs) and Post-treatment Non-serious AEs

6. Other Pre-specified: Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.5 and 0.6 [Time Frame: From start of IMP administration to recovery of T4/T1 Ratio to 0.5 and 0.6 (ranging from ~1 minute to ~4 minutes)]

Measure Type	Other Pre-specified
Measure Title	Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.5 and 0.6
Measure Description	Neuromuscular functioning was monitored by applying repetitive TOF electrical stimulations to the ulnar nerve every 15 seconds & assessing twitch response at the adductor pollicis muscle. T1 and T4 refer to the magnitudes (heights) of the first and fourth twitches, respectively, after TOF nerve stimulation. The T4/T1 Ratio (expressed as a decimal of up to 1.0). Faster times to recovery of the T4/T1 Ratios to 0.5 and 0.6 indicate faster recoveries from NMB.
Time Frame	From start of IMP administration to recovery of T4/T1 Ratio to 0.5 and 0.6 (ranging from ~1 minute to ~4 minutes)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement. No imputation was done for missing times to recovery of the T4/T1 ratio to 0.5 and 0.6.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC

Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	Neostigmine
Number of Participants Analyzed [units: participants]	**66**	**65**
Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.5 and 0.6 [units: minutes] Geometric Mean (95% Confidence Interval)		
Recovery of T4/T1 Ratio to 0.5	**1.3 (1.2 to 1.5)**	**2.8 (2.5 to 3.1)**
Recovery of T4/T1 Ratio to 0.6	**1.5 (1.3 to 1.6)**	**3.4 (3.1 to 3.8)**

No statistical analysis provided for Time From Start of Administration of IMP to Recovery of the T4/T1 Ratio to 0.5 and 0.6

7. Other Pre-specified: Time From Start of Administration of the Last Dose of Rocuronium to Recovery of the T4/T1 Ratio to 0.5, 0.6, 0.7, 0.8 and 0.9 [Time Frame: From start of last dose of rocuronium to recovery of T4/T1 Ratio to 0.5, 0.6, 0.7, 0.8 and 0.9 (ranging from ~12 minutes to ~36 minutes)]

Measure Type	Other Pre-specified
Measure Title	Time From Start of Administration of the Last Dose of Rocuronium to Recovery of the T4/T1 Ratio to 0.5, 0.6, 0.7, 0.8 and 0.9
Measure Description	Neuromuscular functioning was monitored by applying repetitive TOF electrical stimulations to the ulnar nerve every 15 seconds & assessing twitch response at the adductor pollicis muscle. T1 and T4 refer to the magnitudes (heights) of the first and fourth twitches, respectively, after TOF nerve stimulation. The T4/T1 Ratio (expressed as a decimal of up to 1.0). A faster time to recovery of the T4/T1 Ratio indicates a faster recovery from NMB.
Time Frame	From start of last dose of rocuronium to recovery of T4/T1 Ratio to 0.5, 0.6, 0.7, 0.8 and 0.9 (ranging from ~12 minutes to ~36 minutes)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement. No imputation was done for missing times from administration of last dose of rocuronium to recovery of the T4/T1 ratio to 0.5, 0.6, 0.7, 0.8 and 0.9.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	Neostigmine
Number of Participants Analyzed [units: participants]	**66**	**65**
Time From Start of Administration of the Last Dose of Rocuronium to Recovery of the T4/T1 Ratio to 0.5, 0.6, 0.7, 0.8 and 0.9 [units: minutes] Geometric Mean (95% Confidence Interval)		
Recovery of T4/T1 ratio to 0.5	**11.7 (10.1 to 13.6)**	**30.0 (26.2 to 34.4)**
Recovery of T4/T1 ratio to 0.6	**11.9 (10.3 to 13.8)**	**30.7 (26.8 to 35.1)**
Recovery of T4/T1 ratio to 0.7	**12.1 (10.5 to 14.0)**	**31.6 (27.7 to 36.0)**
Recovery of T4/T1 ratio to 0.8	**12.5 (10.8 to 14.3)**	**33.2 (29.2 to 37.9)**
Recovery of T4/T1 ratio to 0.9 (N=65, N=61)	**13.3 (11.6 to 15.3)**	**35.2 (30.8 to 40.2)**

No statistical analysis provided for Time From Start of Administration of the Last Dose of Rocuronium to Recovery of the T4/T1 Ratio to 0.5, 0.6, 0.7, 0.8 and 0.9

8. Other Pre-specified: Time From Start of Administration of the Last Dose of Rocuronium to the Time of 1-2 PTC in the 4.0 mg.Kg-1 Sugammadex Group [Time Frame: From last dose of rocuronium to 1-2 PTC (up to ~9 minutes)]

Measure Type	Other Pre-specified
Measure Title	Time From Start of Administration of the Last Dose of Rocuronium to the Time of 1-2 PTC in the 4.0 mg.Kg-1 Sugammadex Group
Measure Description	The time of 1-2 PTC refers to when 1-2 twitches are generated after tetanic stimulation. Time to 1-2 PTC is the time point of the last single twitch >0 or baseline (in case of noise or direct stimulation) within the sequence of a PTC measurement. 1-2 PTC was the target depth of NMB at which sugammadex was to be administered.
Time Frame	From last dose of rocuronium to 1-2 PTC (up to ~9 minutes)
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 ITT Population consisted of all randomized participants who received sugammadex and had at least one efficacy measurement. The participants who received neostigmine were not included in this analysis.

Reporting Groups

	Description
Sugammadex Only	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC

Measured Values

	Sugammadex Only
Number of Participants Analyzed [units: participants]	**66**
Time From Start of Administration of the Last Dose of Rocuronium to the Time of 1-2 PTC in the 4.0 mg.Kg-1 Sugammadex Group [units: minutes] Geometric Mean (95% Confidence Interval)	**8.9 (7.3 to 10.8)**

No statistical analysis provided for Time From Start of Administration of the Last Dose of Rocuronium to the Time of 1-2 PTC in the 4.0 mg.Kg-1 Sugammadex Group

9. Other Pre-specified: Time From Start of Administration of the Last Dose of Rocuronium to the Time of Reappearance of T2 in the 50 µg.Kg-1 Neostigmine Group [Time Frame: From last dose of rocuronium to reappearance of T2 (up to ~26 minutes)]

Measure Type	Other Pre-specified
Measure Title	Time From Start of Administration of the Last Dose of Rocuronium to the Time of Reappearance of T2 in the 50 µg.Kg-1 Neostigmine Group
Measure Description	The time of reappearance of T2 refers to when the second twitch reappears after TOF stimulation. Reappearance of T2 was the target depth of NMB at which neostigmine was to be administered.
Time Frame	From last dose of rocuronium to reappearance of T2 (up to ~26 minutes)
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 ITT Population consisted of all randomized participants who received neostigmine and had at least one efficacy measurement. The participants who received sugammadex were not included in this analysis.

Reporting Groups

	Description
Neostigmine Only	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Neostigmine Only
Number of Participants Analyzed [units: participants]	**65**
Time From Start of Administration of the Last Dose of Rocuronium to the Time of Reappearance of T2 in the 50 µg.Kg-1 Neostigmine Group	**25.6**

[units: minutes] Geometric Mean (95% Confidence Interval)	**(21.8 to 30.0)**

No statistical analysis provided for Time From Start of Administration of the Last Dose of Rocuronium to the Time of Reappearance of T2 in the 50 µg.Kg-1 Neostigmine Group

10. Other Pre-specified: Mean Systolic Blood Pressure [Time Frame: At screening, pre-rocuronium, pre-IMP, at 2, 5, 10, and 30 minutes post-IMP, and at the post-anesthetic visit (the day after surgery)]

Measure Type	Other Pre-specified
Measure Title	Mean Systolic Blood Pressure
Measure Description	Systolic Blood Pressure was measured at screening, before start of rocuronium administration, before start of IMP administration, at 2, 5, 10, 30 minutes post-IMP administration, and at the post-anesthetic visit (the day after surgery).
Time Frame	At screening, pre-rocuronium, pre-IMP, at 2, 5, 10, and 30 minutes post-IMP, and at the post-anesthetic visit (the day after surgery)
Safety Issue	Yes

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 AST Population consisted of all randomized participants who received IMP.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	**Neostigmine**
Number of Participants Analyzed [units: participants]	**66**	**67**
Mean Systolic Blood Pressure [units: mm Hg] Mean (Standard Deviation)		
Screening	**132.7 (17.7)**	**133.9 (19.1)**
Pre-rocuronium	**98.2 (13.9)**	**101.6 (18.2)**
Pre-IMP	**122.1 (16.5)**	**121.3 (18.8)**
2 minutes post-IMP (N=65, N=65)	**122.5 (18.8)**	**122.5 (20.4)**
5 minutes post-IMP	**122.6 (17.7)**	**118.0 (22.3)**
10 minutes post-IMP (N=66, N=66)	**124.0 (17.8)**	**119.3 (23.7)**
30 minutes post-IMP (N=65, N=66)	**132.9 (17.4)**	**131.7 (23.0)**

Post-anesthetic visit (N=66, N=66)	**127.3 (16.6)**	**125.4 (17.1)**

No statistical analysis provided for Mean Systolic Blood Pressure

11. Other Pre-specified: Mean Diastolic Blood Pressure [Time Frame: At screening, pre-rocuronium, pre-IMP, at 2, 5, 10, and 30 minutes post-IMP, and at the post-anesthetic visit (the day after surgery)]

Measure Type	Other Pre-specified
Measure Title	Mean Diastolic Blood Pressure
Measure Description	Diastolic Blood Pressure was measured at screening, before start of rocuronium administration, before start of IMP administration, at 2, 5, 10, 30 minutes post-IMP administration, and at the post-anesthetic visit (the day after surgery).
Time Frame	At screening, pre-rocuronium, pre-IMP, at 2, 5, 10, and 30 minutes post-IMP, and at the post-anesthetic visit (the day after surgery)
Safety Issue	Yes

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 AST Population consisted of all randomized participants who received IMP.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	**Neostigmine**
Number of Participants Analyzed [units: participants]	**66**	**67**
Mean Diastolic Blood Pressure [units: mm Hg] Mean (Standard Deviation)		
Screening	**80.9 (9.9)**	**82.8 (9.4)**
Pre-rocuronium	**58.2 (11.6)**	**58.3 (10.1)**
Pre-IMP	**72.8 (12.1)**	**72.5 (12.8)**
2 minutes post-IMP (N=65, N=65)	**73.4 (11.8)**	**72.6 (11.8)**
5 minutes post-IMP	**72.4 (11.4)**	**69.2 (13.5)**
10 minutes post-IMP (N=66, N=66)	**71.8 (12.8)**	**68.7 (14.9)**
30 minutes post-IMP (N=65, N=66)	**74.3 (10.9)**	**73.1 (13.5)**
Post-anesthetic visit (N=66, N=66)	**76.7 (9.4)**	**75.2 (10.8)**

No statistical analysis provided for Mean Diastolic Blood Pressure

12. Other Pre-specified: Mean Heart Rate [Time Frame: At screening, pre-rocuronium, pre-IMP, at 2, 5, 10, and 30 minutes post-IMP, and at the post-anesthetic visit (the day after surgery)]

Measure Type	Other Pre-specified
Measure Title	Mean Heart Rate
Measure Description	Heart Rate was measured at screening, before start of rocuronium administration, before start of IMP administration, at 2, 5, 10, 30 minutes post-IMP administration, and at the post-anesthetic visit (the day after surgery).
Time Frame	At screening, pre-rocuronium, pre-IMP, at 2, 5, 10, and 30 minutes post-IMP, and at the post-anesthetic visit (the day after surgery)
Safety Issue	Yes

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 AST Population consisted of all randomized participants who received IMP.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	**Neostigmine**
Number of Participants Analyzed [units: participants]	**66**	**67**
Mean Heart Rate [units: beats per minute] Mean (Standard Deviation)		
Screening	**72.9 (11.0)**	**74.6 (11.4)**
Pre-rocuronium	**63.4 (13.4)**	**63.6 (12.4)**
Pre-IMP	**68.3 (11.0)**	**68.0 (12.3)**
2 minutes post-IMP (N=65, N=65)	**66.0 (12.4)**	**65.3 (12.4)**
5 minutes post-IMP	**64.9 (12.3)**	**57.1 (10.8)**
10 minutes post-IMP (N=66, N=66)	**67.3 (12.4)**	**56.3 (11.4)**
30 minutes post-IMP (N=65, N=66)	**73.1 (12.2)**	**65.1 (11.2)**
Post-anesthetic visit (N=66, N=66)	**72.7 (11.7)**	**71.9 (71.9)**

No statistical analysis provided for Mean Heart Rate

13. Other Pre-specified: Number of Participants Who Had Physical Examinations [Time Frame: At screening (within 7 days prior to surgery) and at the post-anesthetic visit (the day after surgery)]

Measure Type	Other Pre-specified
Measure Title	Number of Participants Who Had Physical Examinations
Measure Description	Physical examinations were to be conducted at screening (within 7 days prior to surgery) and at the post-anesthetic visit (the day after surgery).
Time Frame	At screening (within 7 days prior to surgery) and at the post-anesthetic visit (the day after surgery)
Safety Issue	Yes

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 AST Population consisted of all randomized participants who received IMP. As there was no specific physical examination case report form used in this study, data on whether or not a physical examination was conducted were not recorded.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	**Neostigmine**
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Participants Who Had Physical Examinations		

No statistical analysis provided for Number of Participants Who Had Physical Examinations

14. Other Pre-specified: Number of Participants With Train-of-Four- (TOF-) Watch® SX and Arm Board Related Adverse Events [Time Frame: From induction of anesthesia to recovery from NMB (up to ~3 hours)]

Measure Type	Other Pre-specified
Measure Title	Number of Participants With Train-of-Four- (TOF-) Watch® SX and Arm Board Related Adverse Events
Measure Description	Events were to be collected for the entire period of neuromuscular transmission monitoring and were defined as an occurrence that resulted or could have resulted in: death; a serious deterioration in the state of health of a user; an occurrence which might, if it recurred, lead to death or serious deterioration in health; inaccuracy as well as any inadequacy in the labeling or instructions which could cause misuse or incorrect maintenance or adjustment which might lead to a death or serious deterioration in health; an examination of the medical device or the information supplied with the medical device indicated some factor with the potential for an incident involving death or serious deterioration in

	health; malfunction or deterioration in characteristics and/or performance of a medical device, which might lead to death, or serious deterioration in health; technical/medical recalls involving risk of death or serious deterioration in the state of health of the user.
Time Frame	From induction of anesthesia to recovery from NMB (up to ~3 hours)
Safety Issue	Yes

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 AST Population consisted of all randomized participants who received IMP.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	**Neostigmine**
Number of Participants Analyzed [units: participants]	**66**	**67**
Number of Participants With Train-of-Four- (TOF-) Watch® SX and Arm Board Related Adverse Events [units: participants]	**0**	**0**

No statistical analysis provided for Number of Participants With Train-of-Four- (TOF-) Watch® SX and Arm Board Related Adverse Events

15. Other Pre-specified: Number of Participants With Reoccurrence of Neuromuscular Blockade Based on the Train-of-Four- (TOF-) Watch® SX Recording (i.e. a Decline in T4/T1 Ratio From >=0.9 to <0.8 in at Least Three Consecutive TOF Values) [Time Frame: Up to 30 minutes after IMP administration]

Measure Type	Other Pre-specified
Measure Title	Number of Participants With Reoccurrence of Neuromuscular Blockade Based on the Train-of-Four- (TOF-) Watch® SX Recording (i.e. a Decline in T4/T1 Ratio From >=0.9 to <0.8 in at Least Three Consecutive TOF Values)
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. T1 and T4 refer to the magnitudes (heights) of the 1st and 4th twitches, respectively, after TOF stimulation. The T4/T1 Ratio is expressed as a decimal of up to 1.0. A higher ratio indicates greater recovery from NMB. A decline in the T4/T1 ratio from >=0.9 (indicating a recovery from NMB) to <0.8 for at least three consecutive TOF values was considered to be a reoccurrence of NMB.
Time Frame	Up to 30 minutes after IMP administration
Safety Issue	Yes

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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	Neostigmine
Number of Participants Analyzed [units: participants]	**66**	**65**
Number of Participants With Reoccurrence of Neuromuscular Blockade Based on the Train-of-Four- (TOF-) Watch® SX Recording (i.e. a Decline in T4/T1 Ratio From >=0.9 to <0.8 in at Least Three Consecutive TOF Values) [units: participants]	**0**	**0**

No statistical analysis provided for Number of Participants With Reoccurrence of Neuromuscular Blockade Based on the Train-of-Four- (TOF-) Watch® SX Recording (i.e. a Decline in T4/T1 Ratio From >=0.9 to <0.8 in at Least Three Consecutive TOF Values)

16. Other Pre-specified: Number of Participants With Clinical Evidence of Reoccurrence of Neuromuscular Blockade or Residual Neuromuscular Blockade (Routine Oxygen Saturation by Pulse Oximetry and Breath Frequency Measurement) [Time Frame: Up to 24 hours after IMP administration]

Measure Type	Other Pre-specified
Measure Title	Number of Participants With Clinical Evidence of Reoccurrence of Neuromuscular Blockade or Residual Neuromuscular Blockade (Routine Oxygen Saturation by Pulse Oximetry and Breath Frequency Measurement)
Measure Description	Clinical evidence of reoccurrence of NMB or residual NMB was assessed by oxygen saturation (by pulse oximetry) and breath frequency measurements as per routine practice after anesthesia and neuromuscular monitoring.
Time Frame	Up to 24 hours after IMP administration
Safety Issue	Yes

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 AST Population consisted of all randomized participants who received IMP.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	Neostigmine

Number of Participants Analyzed [units: participants]	**66**	**67**
Number of Participants With Clinical Evidence of Reoccurrence of Neuromuscular Blockade or Residual Neuromuscular Blockade (Routine Oxygen Saturation by Pulse Oximetry and Breath Frequency Measurement) [units: participants]	**1**	**0**

No statistical analysis provided for Number of Participants With Clinical Evidence of Reoccurrence of Neuromuscular Blockade or Residual Neuromuscular Blockade (Routine Oxygen Saturation by Pulse Oximetry and Breath Frequency Measurement)

17. Other Pre-specified: Number of Participants With Events Due to a Possible Interaction of Sugammadex With Endogenous Compounds or With Exogenous Compounds Other Than Rocuronium [Time Frame: Up to 7 days after IMP administration]

Measure Type	Other Pre-specified
Measure Title	Number of Participants With Events Due to a Possible Interaction of Sugammadex With Endogenous Compounds or With Exogenous Compounds Other Than Rocuronium
Measure Description	Any evidence of events due to a possible interaction of sugammadex with endogenous compounds or with exogenous compounds other than rocuronium, was to be recorded.
Time Frame	Up to 7 days after IMP administration
Safety Issue	Yes

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 AST Population consisted of all randomized participants who received sugammadex. Participants who received neostigmine were excluded from this analysis.

Reporting Groups

	Description
Sugammadex Only	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC

Measured Values

	Sugammadex Only
Number of Participants Analyzed [units: participants]	**66**
Number of Participants With Events Due to a Possible Interaction of Sugammadex With Endogenous Compounds or With Exogenous Compounds Other Than Rocuronium [units: participants]	**0**

No statistical analysis provided for Number of Participants With Events Due to a Possible Interaction of Sugammadex With Endogenous Compounds or With Exogenous Compounds Other Than Rocuronium

18. Other Pre-specified: Monitoring of Clinical Signs of Recovery According to Routine Anesthetic Procedures at the Trial Sites [Time Frame: Up

to PACU discharge (up to ~4.5 hours)]

Measure Type	Other Pre-specified
Measure Title	Monitoring of Clinical Signs of Recovery According to Routine Anesthetic Procedures at the Trial Sites
Measure Description	The monitoring of clinical signs of recovery was to be conducted based on the routine anesthetic procedures at each site.
Time Frame	Up to PACU discharge (up to ~4.5 hours)
Safety Issue	Yes

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 AST Population consisted of all randomized participants who received IMP.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	**Neostigmine**
Number of Participants Analyzed [units: participants]	**66**	**67**
Monitoring of Clinical Signs of Recovery According to Routine Anesthetic Procedures at the Trial Sites [units: participants]	**NA** [1]	**NA** [1]

[1] This was a site-specific outcome measure. Data were collected at each site, but were not collected on a case report form and were not analyzed.

No statistical analysis provided for Monitoring of Clinical Signs of Recovery According to Routine Anesthetic Procedures at the Trial Sites

19. Other Pre-specified: Number of Female Participants or Partners of Male Participants Who Became Pregnant During Study [Time Frame: Up to 30 days after IMP administration]

Measure Type	Other Pre-specified
Measure Title	Number of Female Participants or Partners of Male Participants Who Became Pregnant During Study
Measure Description	Thirty days after administration of IMP, female participants of childbearing potential were asked whether they became pregnant during the trial and male participants were asked whether their partner (if of childbearing potential) became pregnant during the trial.
Time Frame	Up to 30 days after IMP administration
Safety Issue	Yes

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 AST Population consisted of all randomized participants who received IMP.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	Neostigmine
Number of Participants Analyzed [units: participants]	**66**	**67**
Number of Female Participants or Partners of Male Participants Who Became Pregnant During Study [units: participants]	**0**	**0**

No statistical analysis provided for Number of Female Participants or Partners of Male Participants Who Became Pregnant During Study

20. Other Pre-specified: Time From Operating Room Admission to Operating Room Discharge Ready [Time Frame: From Operating Room admission to Operating Room discharge ready (up to ~3 hours)]

Measure Type	Other Pre-specified
Measure Title	Time From Operating Room Admission to Operating Room Discharge Ready
Measure Description	The time of Operating Room admission was defined as the time at which the participant was physically placed into the Operating Room. The time of Operating Room discharge ready was defined as time at which the participant had T4/T1 ratio of ≥0.9 and the participant's wound dressing was in place.
Time Frame	From Operating Room admission to Operating Room discharge ready (up to ~3 hours)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	Neostigmine

Number of Participants Analyzed [units: participants]	**66**	**65**
Time From Operating Room Admission to Operating Room Discharge Ready [units: minutes] Mean (Standard Deviation)	**154 (46)**	**165 (55)**

No statistical analysis provided for Time From Operating Room Admission to Operating Room Discharge Ready

21. Other Pre-specified: Time From Operating Room Admission to Actual Operating Room Discharge [Time Frame: From Operating Room admission to actual Operating Room discharge (up to ~3 hours)]

Measure Type	Other Pre-specified
Measure Title	Time From Operating Room Admission to Actual Operating Room Discharge
Measure Description	The time of Operating Room admission was defined as the time at which the participant was physically placed into the Operating Room. The time of Operating Room discharge was defined as the actual time the participant was discharged from the Operating Room.
Time Frame	From Operating Room admission to actual Operating Room discharge (up to ~3 hours)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	**Neostigmine**
Number of Participants Analyzed [units: participants]	**66**	**64**
Time From Operating Room Admission to Actual Operating Room Discharge [units: minutes] Mean (Standard Deviation)	**158 (47)**	**169 (58)**

No statistical analysis provided for Time From Operating Room Admission to Actual Operating Room Discharge

22. Other Pre-specified: Time From Operating Room Discharge Ready to Actual Operating Room Discharge [Time Frame: From Operating Room discharge ready to actual Operating Room discharge (up to ~5 minutes)]

Measure Type	Other Pre-specified
Measure Title	Time From Operating Room Discharge Ready to Actual Operating Room Discharge
Measure Description	The time of Operating Room discharge ready was defined as time at which the participant had T4/T1 ratio of >=0.9 and the participant's wound dressing was in place. The time of Operating Room discharge was defined as the actual time the participant was discharged from the Operating Room.
Time Frame	From Operating Room discharge ready to actual Operating Room discharge (up to ~5 minutes)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	**Neostigmine**
Number of Participants Analyzed [units: participants]	**66**	**64**
Time From Operating Room Discharge Ready to Actual Operating Room Discharge [units: minutes] Mean (Standard Deviation)	**4 (5)**	**5 (6)**

No statistical analysis provided for Time From Operating Room Discharge Ready to Actual Operating Room Discharge

23. Other Pre-specified: Time From Start of IMP Administration to T4/T1 Ratio of <=0.60, >0.60 - <=0.70, >0.70 - <=0.80, >0.80 - <0.90 and >=0.90 [Time Frame: From start of IMP administration to recovery of the T4/T1 ratio to the designated value (ranging from ~1 minute to ~10 minutes)]

Measure Type	Other Pre-specified
Measure Title	Time From Start of IMP Administration to T4/T1 Ratio of <=0.60, >0.60 - <=0.70, >0.70 - <=0.80, >0.80 - <0.90 and >=0.90
Measure Description	The time of IMP administration was defined as the actual time at which IMP administration was started.
Time Frame	From start of IMP administration to recovery of the T4/T1 ratio to the designated value (ranging from ~1 minute to ~10 minutes)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement. Data not collected. In Protocol Amendment 2, this outcome measure was removed.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	Neostigmine
Number of Participants Analyzed [units: participants]	**0**	**0**
Time From Start of IMP Administration to T4/T1 Ratio of <=0.60, >0.60 - <=0.70, >0.70 - <=0.80, >0.80 - <0.90 and >=0.90		

No statistical analysis provided for Time From Start of IMP Administration to T4/T1 Ratio of <=0.60, >0.60 - <=0.70, >0.70 - <=0.80, >0.80 - <0.90 and >=0.90

24. Other Pre-specified: Time From Start of IMP Administration to Tracheal Extubation [Time Frame: From start of IMP administration to tracheal extubation (up to ~21 minutes)]

Measure Type	Other Pre-specified
Measure Title	Time From Start of IMP Administration to Tracheal Extubation
Measure Description	The time of IMP administration was defined as the actual time at which IMP administration was started. The time of tracheal extubation was defined as the actual time at which the participant was extubated.
Time Frame	From start of IMP administration to tracheal extubation (up to ~21 minutes)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	Neostigmine
Number of Participants Analyzed		

[units: participants]	**66**	**65**
Time From Start of IMP Administration to Tracheal Extubation **[units: minutes]** **Mean (Standard Deviation)**	**14 (8)**	**21 (11)**

No statistical analysis provided for Time From Start of IMP Administration to Tracheal Extubation

25. Other Pre-specified: Time From Start of IMP Administration to Operating Room Discharge Ready [Time Frame: From start of IMP administration to Operating Room discharge ready (up to ~21 minutes)]

Measure Type	Other Pre-specified
Measure Title	Time From Start of IMP Administration to Operating Room Discharge Ready
Measure Description	The time of IMP administration was defined as the actual time at which IMP administration was started. The time of Operating Room discharge ready was defined as time at which the participant had T4/T1 ratio of >=0.9 and the participant's wound dressing was in place.
Time Frame	From start of IMP administration to Operating Room discharge ready (up to ~21 minutes)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	**Neostigmine**
Number of Participants Analyzed **[units: participants]**	**66**	**65**
Time From Start of IMP Administration to Operating Room Discharge Ready **[units: minutes]** **Mean (Standard Deviation)**	**15 (8)**	**21 (11)**

No statistical analysis provided for Time From Start of IMP Administration to Operating Room Discharge Ready

26. Other Pre-specified: Time From Start of IMP Administration to Actual Operating Room Discharge [Time Frame: From start of IMP administration to actual Operating Room discharge (up to ~26 minutes)]

Measure Type	Other Pre-specified

Measure Title	Time From Start of IMP Administration to Actual Operating Room Discharge
Measure Description	The time of IMP administration was defined as the actual time at which IMP administration was started. The time of Operating Room discharge was defined as the actual time at which the participant was discharged from the Operating Room.
Time Frame	From start of IMP administration to actual Operating Room discharge (up to ~26 minutes)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	**Neostigmine**
Number of Participants Analyzed [units: participants]	**66**	**64**
Time From Start of IMP Administration to Actual Operating Room Discharge [units: minutes] Mean (Standard Deviation)	**19 (9)**	**26 (13)**

No statistical analysis provided for Time From Start of IMP Administration to Actual Operating Room Discharge

27. Other Pre-specified: Time From Tracheal Extubation to Operating Room Discharge Ready [Time Frame: From tracheal extubation to Operating Room discharge ready (up to ~1 minute)]

Measure Type	Other Pre-specified
Measure Title	Time From Tracheal Extubation to Operating Room Discharge Ready
Measure Description	The time of tracheal extubation was defined as the actual time at which the participant was extubated. The time of Operating Room discharge ready was defined as time at which the participant had T4/T1 ratio of >=0.9 and the participant's wound dressing was in place.
Time Frame	From tracheal extubation to Operating Room discharge ready (up to ~1 minute)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	Neostigmine
Number of Participants Analyzed [units: participants]	**66**	**65**
Time From Tracheal Extubation to Operating Room Discharge Ready [units: minutes] Mean (Standard Deviation)	**1 (6)**	**0 (6)**

No statistical analysis provided for Time From Tracheal Extubation to Operating Room Discharge Ready

28. Other Pre-specified: Time From Tracheal Extubation to Actual Operating Room Discharge [Time Frame: From tracheal extubation to actual OR discharge (up to ~5 minutes)]

Measure Type	Other Pre-specified
Measure Title	Time From Tracheal Extubation to Actual Operating Room Discharge
Measure Description	The time of tracheal extubation was defined as the actual time at which the participant was extubated. The time of Operating Room discharge was defined as the actual time at which the participant was discharged from the Operating Room.
Time Frame	From tracheal extubation to actual OR discharge (up to ~5 minutes)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	Neostigmine
Number of Participants Analyzed [units: participants]	**66**	**64**

Time From Tracheal Extubation to Actual Operating Room Discharge **[units: minutes]** **Mean (Standard Deviation)**	**5 (7)**	**5 (6)**

No statistical analysis provided for Time From Tracheal Extubation to Actual Operating Room Discharge

29. Other Pre-specified: Time From Operating Room Discharge Ready to Post Anesthetic Care Unit (PACU) Discharge Ready [Time Frame: From Operating Room discharge ready to PACU discharge ready (up to ~33 minutes)]

Measure Type	Other Pre-specified
Measure Title	Time From Operating Room Discharge Ready to Post Anesthetic Care Unit (PACU) Discharge Ready
Measure Description	The time of Operating Room discharge ready was defined as time at which the participant had T4/T1 ratio of >=0.9 and the participant's wound dressing was in place. The time of PACU discharge ready was defined as the time at which the participant had a Modified Aldrete Score >=9. The Modified Aldrete Score was to be assessed at PACU arrival, at 5, 15, 30, 45, 60 minutes after PACU arrival and every 15 minutes thereafter (if applicable) until the participant was ready to be discharged from the PACU. The Modified Aldrete Postoperative Recovery Score (range = 0-10) is calculated based on scores of 0 to 2 each for Activity, Respiration, Circulation, Consciousness and Oxygen Saturation, with a higher score indicating increased postoperative recovery.
Time Frame	From Operating Room discharge ready to PACU discharge ready (up to ~33 minutes)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	**Neostigmine**
Number of Participants Analyzed **[units: participants]**	**66**	**65**
Time From Operating Room Discharge Ready to Post Anesthetic Care Unit (PACU) Discharge Ready **[units: minutes]** **Mean (Standard Deviation)**	**28 (27)**	**33 (40)**

No statistical analysis provided for Time From Operating Room Discharge Ready to Post Anesthetic Care Unit (PACU) Discharge Ready

30. Other Pre-specified: Time From Operating Room Discharge Ready to Actual PACU Discharge [Time Frame: From Operating Room discharge ready to actual PACU discharge (up to ~4.5 hours)]

Measure Type	Other Pre-specified
Measure Title	Time From Operating Room Discharge Ready to Actual PACU Discharge
Measure Description	The time of Operating Room discharge ready was defined as time at which the participant had T4/T1 ratio of >=0.9 and the participant's wound dressing was in place. The time of PACU discharge was defined as the actual time the participant was discharged from the PACU.
Time Frame	From Operating Room discharge ready to actual PACU discharge (up to ~4.5 hours)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	**Neostigmine**
Number of Participants Analyzed [units: participants]	**66**	**65**
Time From Operating Room Discharge Ready to Actual PACU Discharge [units: minutes] Mean (Standard Deviation)	**268 (348)**	**210 (283)**

No statistical analysis provided for Time From Operating Room Discharge Ready to Actual PACU Discharge

31. Other Pre-specified: Time From Actual Operating Room Discharge to PACU Discharge Ready [Time Frame: From actual Operating Room discharge to PACU discharge ready (up to ~30 minutes)]

Measure Type	Other Pre-specified
Measure Title	Time From Actual Operating Room Discharge to PACU Discharge Ready
Measure Description	The time of Operating Room discharge was defined as the actual time the participant was discharged from the Operating Room. The time of PACU discharge ready was defined as the time at which the participant had a Modified Aldrete Score >=9. The Modified Aldrete Score was to be assessed at PACU arrival, at 5, 15, 30, 45, 60 minutes after PACU arrival and every 15 minutes thereafter (if applicable) until the participant was ready to be discharged from the PACU. The Modified Aldrete Postoperative Recovery Score (range = 0-10) is calculated based on scores of 0 to 2 each for Activity, Respiration, Circulation, Consciousness and Oxygen Saturation, with a higher score indicating increased postoperative recovery.
Time Frame	From actual Operating Room discharge to PACU discharge ready (up to ~30 minutes)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	**Neostigmine**
Number of Participants Analyzed [units: participants]	**66**	**64**
Time From Actual Operating Room Discharge to PACU Discharge Ready [units: minutes] Mean (Standard Deviation)	**24 (28)**	**29 (40)**

No statistical analysis provided for Time From Actual Operating Room Discharge to PACU Discharge Ready

32. Other Pre-specified: Time From Actual Operating Room Discharge to Actual PACU Discharge [Time Frame: From actual Operating Room discharge to actual PACU discharge (up to ~4.4 hours)]

Measure Type	Other Pre-specified
Measure Title	Time From Actual Operating Room Discharge to Actual PACU Discharge
Measure Description	The time of Operating Room discharge was defined as the actual time the participant was discharged from the Operating Room. The time of PACU discharge was defined as the actual time the participant was discharged from the PACU.
Time Frame	From actual Operating Room discharge to actual PACU discharge (up to ~4.4 hours)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	Neostigmine
Number of Participants Analyzed [units: participants]	**66**	**64**
Time From Actual Operating Room Discharge to Actual PACU Discharge [units: minutes] Mean (Standard Deviation)	**264 (347)**	**207 (284)**

No statistical analysis provided for Time From Actual Operating Room Discharge to Actual PACU Discharge

33. Other Pre-specified: Time From PACU Admit to PACU Discharge Ready [Time Frame: From PACU admit to PACU discharge ready (up to ~25 minutes)]

Measure Type	Other Pre-specified
Measure Title	Time From PACU Admit to PACU Discharge Ready
Measure Description	The time of PACU admit was defined as the actual time the participant was admitted to the PACU. The time of PACU discharge ready was defined as the time at which the participant had a Modified Aldrete Score >=9. The Modified Aldrete Score was to be assessed at PACU arrival, at 5, 15, 30, 45, 60 minutes after PACU arrival and every 15 minutes thereafter (if applicable) until the participant was ready to be discharged from the PACU. The Modified Aldrete Postoperative Recovery Score (range = 0-10) is calculated based on scores of 0 to 2 each for Activity, Respiration, Circulation, Consciousness and Oxygen Saturation, with a higher score indicating increased postoperative recovery.
Time Frame	From PACU admit to PACU discharge ready (up to ~25 minutes)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	Neostigmine
Number of Participants Analyzed [units: participants]	**66**	**64**
Time From PACU Admit to PACU Discharge Ready [units: minutes] Mean (Standard Deviation)	**20 (28)**	**25 (40)**

No statistical analysis provided for Time From PACU Admit to PACU Discharge Ready

34. Other Pre-specified: Time From PACU Admit to Actual PACU Discharge [Time Frame: From PACU admit to actual PACU discharge (up to ~4.3 hours)]

Measure Type	Other Pre-specified
Measure Title	Time From PACU Admit to Actual PACU Discharge
Measure Description	The time of PACU admit was defined as the actual time the participant was admitted to the PACU. The time of PACU discharge was defined as the actual time the participant was discharged from the PACU.
Time Frame	From PACU admit to actual PACU discharge (up to ~4.3 hours)
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 ITT Population consisted of all randomized participants who received IMP and had at least one efficacy measurement.

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine:atropine) at reappearance of T2

Measured Values

	Sugammadex	**Neostigmine**
Number of Participants Analyzed [units: participants]	**66**	**64**
Time From PACU Admit to Actual PACU Discharge [units: minutes] Mean (Standard Deviation)	**260 (347)**	**203 (284)**

No statistical analysis provided for Time From PACU Admit to Actual PACU Discharge

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 7 days after IMP administration
Additional Description	The AST Population consisted of all randomized participants who received IMP. • Serious Adverse Events (SAEs) include both pre-treatment (from signing of informed consent to start of IMP administration) and post-treatment (from start of IMP administration to 7 days after IMP administration) SAEs.

Reporting Groups

	Description

Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine: atropine) at reappearance of T2

Serious Adverse Events

	Sugammadex	Neostigmine
Total, serious adverse events		
# participants affected / at risk	**5/66 (7.58%)**	**6/67 (8.96%)**
Gastrointestinal disorders		
Colitis [1]		
# participants affected / at risk	**1/66 (1.52%)**	**0/67 (0.00%)**
# events	**1**	**0**
Pancreatitis acute [1]		
# participants affected / at risk	**0/66 (0.00%)**	**1/67 (1.49%)**
# events	**0**	**1**
Injury, poisoning and procedural complications		
Operative haemorrhage [1]		
# participants affected / at risk	**0/66 (0.00%)**	**1/67 (1.49%)**
# events	**0**	**1**
Post procedural complication [1]		
# participants affected / at risk	**1/66 (1.52%)**	**1/67 (1.49%)**
# events	**1**	**1**
Procedural nausea [1]		
# participants affected / at risk	**1/66 (1.52%)**	**0/67 (0.00%)**
# events	**1**	**0**
Procedural pain [1]		
# participants affected / at risk	**0/66 (0.00%)**	**1/67 (1.49%)**
# events	**0**	**1**
Procedural vomiting [1]		
# participants affected / at risk	**1/66 (1.52%)**	**0/67 (0.00%)**
# events	**1**	**0**
Musculoskeletal and connective tissue disorders		
Muscle rigidity [1]		
# participants affected / at risk	**1/66 (1.52%)**	**0/67 (0.00%)**
# events	**1**	**0**
Nervous system disorders		
Sedation [1]		
# participants affected / at risk	**0/66 (0.00%)**	**1/67 (1.49%)**
# events	**0**	**1**
Vascular disorders		
Vascular calcification [1]		
# participants affected / at risk	**1/66 (1.52%)**	**0/67 (0.00%)**
# events	**1**	**0**

Vascular thrombosis limb [1]		
# participants affected / at risk	**0/66 (0.00%)**	**1/67 (1.49%)**
# events	**0**	**1**

1 Term from vocabulary, MedDRA 12.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 7 days after IMP administration
Additional Description	The AST Population consisted of all randomized participants who received IMP. • Serious Adverse Events (SAEs) include both pre-treatment (from signing of informed consent to start of IMP administration) and post-treatment (from start of IMP administration to 7 days after IMP administration) SAEs.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Sugammadex	Participants receiving 4.0 mg.kg-1 sugammadex at 1-2 PTC
Neostigmine	Participants receiving 50 µg.kg-1 neostigmine (with atropine in a ratio of 5:1 for neostigmine: atropine) at reappearance of T2

Other Adverse Events

	Sugammadex	**Neostigmine**
Total, other (not including serious) adverse events		
# participants affected / at risk	**64/66 (96.97%)**	**63/67 (94.03%)**
Gastrointestinal disorders		
Abdominal Pain [1]		
# participants affected / at risk	**5/66 (7.58%)**	**4/67 (5.97%)**
# events	**5**	**4**
Constipation [1]		
# participants affected / at risk	**6/66 (9.09%)**	**3/67 (4.48%)**
# events	**6**	**3**
Dry mouth [1]		
# participants affected / at risk	**0/66 (0.00%)**	**4/67 (5.97%)**
# events	**0**	**4**
Flatulence [1]		
# participants affected / at risk	**2/66 (3.03%)**	**4/67 (5.97%)**
# events	**2**	**4**
Nausea [1]		
# participants affected / at risk	**16/66 (24.24%)**	**12/67 (17.91%)**

# events	17	13
Vomiting [1]		
# participants affected / at risk	8/66 (12.12%)	7/67 (10.45%)
# events	8	7
Injury, poisoning and procedural complications		
Anaesthetic complication cardiac [1]		
# participants affected / at risk	1/66 (1.52%)	9/67 (13.43%)
# events	1	9
Procedural nausea [1]		
# participants affected / at risk	3/66 (4.55%)	5/67 (7.46%)
# events	3	5
Procedural pain [1]		
# participants affected / at risk	60/66 (90.91%)	60/67 (89.55%)
# events	70	72
Procedural vomiting [1]		
# participants affected / at risk	3/66 (4.55%)	5/67 (7.46%)
# events	3	5
Investigations		
C-reactive protein increased [1]		
# participants affected / at risk	8/66 (12.12%)	6/67 (8.96%)
# events	8	6
Musculoskeletal and connective tissue disorders		
Musculoskeletal pain [1]		
# participants affected / at risk	5/66 (7.58%)	3/67 (4.48%)
# events	5	3

1 Term from vocabulary, MedDRA 12.1

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 **NOT** 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.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development

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Publications of Results:

Geldner G, Niskanen M, Laurila P, Mizikov V, Hübler M, Beck G, Rietbergen H, Nicolayenko E. A randomised controlled trial comparing sugammadex and neostigmine at different depths of neuromuscular blockade in patients undergoing laparoscopic surgery. Anaesthesia. 2012 Sep;67(9):991-8. doi: 10.1111/j.1365-2044.2012.07197.x. Epub 2012 Jun 14.

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Aldrete JA, Kroulik D. A postanesthetic recovery score. Anesth Analg. 1970 Nov-Dec;49(6):924-34.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00724932 History of Changes
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Study First Received:	July 28, 2008
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Last Updated:	February 26, 2015
Health Authority:	Finland: Finnish Medicines Agency Germany: Federal Institute for Drugs and Medical Devices Russia: Ministry of Health of the Russian Federation United Kingdom: Medicines and Healthcare Products Regulatory Agency

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