Comparison of 4.0 mg/kg Sugammadex at 1-2 Post Tetanic Counts (PTC) in Renal or Control Patients (19.4.328)(P05769)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00702715

First received: June 19, 2008
Last updated: May 11, 2015
Last verified: May 2015
History of Changes

Purpose

The current trial was designed to investigate the effects of 4.0 mg.kg-1 of sugammadex on efficacy, safety and pharmacokinetics in subjects with severe renal impairment in comparison to subjects with normal renal function.

Condition	Intervention	Phase
Anesthesia	Drug: sugammadex	Phase 3

Study Type: Interventional
Study Design: Allocation: Non-Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Multi-center, Parallel-group, Comparative Trial Evaluating the Efficacy, Pharmacokinetics and Safety of 4.0 mg/kg Sugammadex Administered at 1-2 PTC in Subjects With Normal or Severely Impaired Renal Function

Resource links provided by NLM:

Drug Information available for: Sugammadex Sugammadex sodium

U.S. FDA Resources

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

Primary Outcome Measures:

- Time to Recovery of the T4/T1 Ratio to 0.9. [Time Frame: start of administration of sugammadex to recovery from neuromuscular blockade] [Designated as safety issue: No]

Neuromuscular functioning was monitored by applying repetitive train of four (TOF) electrical stimulations to the ulnar nerve every 15 seconds and assessing twitch response at the adductor pollicis muscle. Nerve stimulation continued until the ratio of the magnitude of the fourth twitch (T4) to first twitch (T1) reached at least 0.9. The greater the T4/T1 ratio the greater the recovery from neuromuscular blockade, with a value of 1.0 representing full recovery.

Secondary Outcome Measures:

- Time to Recovery of the T4/T1 Ratio to 0.8 [Time Frame: start of administration of sugammadex to recovery from neuromuscular blockade] [Designated as safety issue: No]

  Neuromuscular functioning was monitored by applying repetitive train of four (TOF) electrical stimulations to the ulnar nerve every 15 seconds and assessing twitch response at the adductor pollicis muscle. Nerve stimulation continued until the ratio of the magnitude of the fourth twitch (T4) to first twitch (T1) reached at least 0.9. The greater the T4/T1 ratio the greater the recovery from neuromuscular blockade, with a value of 1.0 representing full recovery.

- Time to Recovery of T4/T1 Ratio to 0.7 [Time Frame: start of administration of sugammadex to recovery from neuromuscular blockade] [Designated as safety issue: No]

  Neuromuscular functioning was monitored by applying repetitive train of four (TOF) electrical stimulations to the ulnar nerve every 15 seconds and assessing twitch response at the adductor pollicis muscle. Nerve stimulation continued until the ratio of the magnitude of the fourth twitch (T4) to first twitch (T1) reached at least 0.9. The greater the T4/T1 ratio the greater the recovery from neuromuscular blockade, with a value of 1.0 representing full recovery.

Enrollment:	69
Study Start Date:	September 2008
Study Completion Date:	March 2010
Primary Completion Date:	March 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Participants with severe renal impairment Participants with severe renal impairment will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 PTC. Severe renal impairment was defined as creatinine clearance <30mL/min.	Drug: sugammadex Each subject 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. In case of maintenance dosing, the target depth of neuromuscular blockade has to be maintained at 1-2 post-tetanic counts (PTC). After the last dose of rocuronium has been administered, the subject will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 PTC. Other Name: Org 25959
Active Comparator: Participants with normal renal function Participants with normal renal impairment will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 PTC. Normal renal function was defined as creatinine clearance >=80mL/min.	Drug: sugammadex Each subject 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. In case of maintenance dosing, the target depth of neuromuscular blockade has to be maintained at 1-2 post-tetanic counts (PTC). After the last dose of rocuronium has been administered, the subject will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 PTC. Other Name: Org 25959

Detailed Description:

The results of previous trials showed that the safety profile of sugammadex observed in subjects with impaired renal function are not appreciably different from subjects with normal renal function. Reoccurrence of

neuromuscular blockade was not observed, and sugammadex was safe and generally well tolerated in subjects with severe renal impairment. In a previous trial, subjects (n=15) with severe renal impairment received a dose of 2.0 mg.kg-1 of sugammadex. The effects of the other proposed recommended dose for routine reversal, 4.0 mg.kg-1, on efficacy, safety and pharmacokinetics had not been studied thus far in subjects with severe renal impairment. The objectives of this trial were to assess equivalence with respect to the efficacy of sugammadex in subjects with normal renal function or severe renal impairment, to evaluate the safety of sugammadex in these subject groups and to compare the pharmacokinetic profiles.

Eligibility

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

Criteria

Inclusion Criteria:

- At least 18 years of age
- ASA class 1-3
- Creatinine clearance (CLcr) < 30 mL/min and no anticipated clinical

indication for high flux hemodialysis during first 24 hours after

sugammadex administration (for renally impaired group) or CLcr >= 80

mL/min (for control group)

-Scheduled for a surgical procedure under general anesthesia with propofol

requiring neuromuscular relaxation with the use of rocuronium

- Scheduled for a surgical procedure in supine position
- Written informed consent

Exclusion Criteria:

- Subjects known or suspected to have neuromuscular disorders impairing

neuromuscular blockade and/or significant hepatic dysfunction

- Subjects scheduled for renal transplant surgery
- Subjects known or suspected to have a (family) history of malignant

hyperthermia

-Subjects known or suspected to have an allergy to narcotics, muscle

relaxants or other medication used during general anesthesia

- Subjects receiving fusidic acid, toremifene and/or flucloxacillin
- Subjects who have already participated in a sugammadex trial
- Subjects who have participated in another clinical trial, not pre-approved

by the sponsor, within 30 days of entering into 19.4.328 (P05769)

- Female subjects who are pregnant
- Female subjects who are breast-feeding

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:

Panhuizen IF, Gold SJ, Buerkle C, Snoeck MM, Harper NJ, Kaspers MJ, van den Heuvel MW, Hollmann MW. Efficacy, safety and pharmacokinetics of sugammadex 4 mg kg-1 for reversal of deep neuromuscular blockade in patients with severe renal impairment. Br J Anaesth.

2015 May;114(5):777-84. doi: 10.1093/bja/aet586. Epub 2015 Mar 31.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00702715 History of Changes
Other Study ID Numbers:	P05769 19.4.328
Study First Received:	June 19, 2008
Results First Received:	March 15, 2011
Last Updated:	May 11, 2015
Health Authority:	France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)

ClinicalTrials.gov processed this record on April 10, 2016

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Results First Received: March 15, 2011

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Anesthesia
Intervention:	Drug: sugammadex

Participant Flow

Hide Participant Flow

Recruitment Details

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

Pre-Assignment Details

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

Reporting Groups

	Description
Participants With Severe Renal Impairment	

	Participants with severe renal impairment will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 post-tetanic counts (PTC). Severe renal impairment was defined as creatinine clearance <30mL/min.
Participants With Normal Renal Function	Participants with normal renal impairment will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 PTC. Normal renal function was defined as creatinine clearance >=80mL/min.

Participant Flow: Overall Study

	Participants With Severe Renal Impairment	Participants With Normal Renal Function
STARTED	35	33 [1]
COMPLETED	34	33
NOT COMPLETED	1	0
Lost to Follow-up	1	0

[1] One subject was enrolled but did not start study

Baseline Characteristics

Hide Baseline Characteristics

Population Description

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

Reporting Groups

	Description
Participants With Severe Renal Impairment	Participants with severe renal impairment will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 PTC. Severe renal impairment was defined as creatinine clearance <30mL/min.
Participants With Normal Renal Function	Participants with normal renal impairment will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 PTC. Normal renal function was defined as creatinine clearance >=80mL/min.
Total	Total of all reporting groups

Baseline Measures

	Participants With Severe Renal Impairment	Participants With Normal Renal Function	Total
Number of Participants [units: participants]	35	33	68
Age [units: years] Mean (Standard Deviation)	57 (16)	45 (15)	51 (16)
Gender [units: participants]			
Female	17	13	30
Male	18	20	38

Outcome Measures

Hide All Outcome Measures

1. Primary: Time to Recovery of the T4/T1 Ratio to 0.9. [Time Frame: start of administration of sugammadex to recovery from neuromuscular blockade]

Measure Type	Primary
Measure Title	Time to Recovery of the T4/T1 Ratio to 0.9.
Measure Description	Neuromuscular functioning was monitored by applying repetitive train of four (TOF) electrical stimulations to the ulnar nerve every 15 seconds and assessing twitch response at the adductor pollicis muscle. Nerve stimulation continued until the ratio of the magnitude of the fourth twitch (T4) to first twitch (T1) reached at least 0.9. The greater the T4/T1 ratio the greater the recovery from neuromuscular blockade, with a value of 1.0 representing full recovery.
Time Frame	start of administration of sugammadex to recovery from neuromuscular blockade
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Analysis performed using the Intent-to-Treat (ITT) Population, which consisted of all treated subjects who had at least one efficacy measurement.

Reporting Groups

	Description
Participants With Severe Renal Impairment	Participants with severe renal impairment will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 PTC. Severe renal impairment was defined as creatinine clearance <30mL/min.
Participants With Normal Renal Function	Participants with normal renal impairment will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 PTC. Normal renal function was defined as creatinine clearance >=80mL/min.

Measured Values

	Participants With Severe Renal Impairment	**Participants With Normal Renal Function**
Number of Participants Analyzed [units: participants]	**35**	**32**
Time to Recovery of the T4/T1 Ratio to 0.9. [units: seconds] Geometric Mean (95% Confidence Interval)	**205 (169 to 248)**	**112 (92 to 138)**

Statistical Analysis 1 for Time to Recovery of the T4/T1 Ratio to 0.9.

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	Hodges-Lehmann and Moses

Median Difference (Final Values) [4]	78.0
95% Confidence Interval	36.0 to 143.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	The 95% confidence interval for the estimated median treatment difference in recovery time must have fallen entirely within the pre-specified interval between -60 sec to +60 sec in order to claim equivalence
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[4]	Other relevant estimation information:
	Estimated median treatment difference (severe renal impairment minus normal renal function) in recovery time (seconds)

2. Secondary: Time to Recovery of the T4/T1 Ratio to 0.8 [Time Frame: start of administration of sugammadex to recovery from neuromuscular blockade]

Measure Type	Secondary
Measure Title	Time to Recovery of the T4/T1 Ratio to 0.8
Measure Description	Neuromuscular functioning was monitored by applying repetitive train of four (TOF) electrical stimulations to the ulnar nerve every 15 seconds and assessing twitch response at the adductor pollicis muscle. Nerve stimulation continued until the ratio of the magnitude of the fourth twitch (T4) to first twitch (T1) reached at least 0.9. The greater the T4/T1 ratio the greater the recovery from neuromuscular blockade, with a value of 1.0 representing full recovery.
Time Frame	start of administration of sugammadex to recovery from neuromuscular blockade
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Analysis performed using the Intent-to-Treat (ITT) Population, which consisted of all treated subjects who had at least one efficacy measurement.

Reporting Groups

	Description
Participants With Severe Renal Impairment	Participants with severe renal impairment will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 PTC. Severe renal impairment was defined as creatinine clearance <30mL/min.
Participants With Normal Renal Function	Participants with normal renal impairment will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 PTC. Normal renal function was defined as creatinine clearance >=80mL/min.

Measured Values

	Participants With Severe Renal Impairment	**Participants With Normal Renal Function**
Number of Participants Analyzed [units: participants]	**35**	**32**

Time to Recovery of the T4/T1 Ratio to 0.8 **[units: seconds]** **Geometric Mean (95% Confidence Interval)**	**169 (141 to 203)**	**90 (76 to 107)**

Statistical Analysis 1 for Time to Recovery of the T4/T1 Ratio to 0.8

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	Hodges-Lehmann and Moses
Median Difference (Final Values) [4]	68.0
95% Confidence Interval	36.0 to 120.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	For the secondary endpoint no equivalence margin was specified (i.e., no formal null-hypothesis was specified); the median difference and associated 95% CI were to further characterize the efficacy of severe renal impaired subjects and controls.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[4]	Other relevant estimation information:
	Estimated median treatment difference (severe renal impairment minus normal renal function) in recovery time (seconds)

3. Secondary: Time to Recovery of T4/T1 Ratio to 0.7 [Time Frame: start of administration of sugammadex to recovery from neuromuscular blockade]

Measure Type	Secondary
Measure Title	Time to Recovery of T4/T1 Ratio to 0.7
Measure Description	Neuromuscular functioning was monitored by applying repetitive train of four (TOF) electrical stimulations to the ulnar nerve every 15 seconds and assessing twitch response at the adductor pollicis muscle. Nerve stimulation continued until the ratio of the magnitude of the fourth twitch (T4) to first twitch (T1) reached at least 0.9. The greater the T4/T1 ratio the greater the recovery from neuromuscular blockade, with a value of 1.0 representing full recovery.
Time Frame	start of administration of sugammadex to recovery from neuromuscular blockade
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Analysis performed using the Intent-to-Treat (ITT) Population, which consisted of all treated subjects who had at least one efficacy measurement.

Reporting Groups

	Description

Participants With Severe Renal Impairment	Participants with severe renal impairment will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 PTC. Severe renal impairment was defined as creatinine clearance <30mL/min.
Participants With Normal Renal Function	Participants with normal renal impairment will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 PTC. Normal renal function was defined as creatinine clearance >=80mL/min.

Measured Values

	Participants With Severe Renal Impairment	Participants With Normal Renal Function
Number of Participants Analyzed [units: participants]	**35**	**32**
Time to Recovery of T4/T1 Ratio to 0.7 [units: seconds] Geometric Mean (95% Confidence Interval)	**144 (120 to 172)**	**79 (67 to 92)**

Statistical Analysis 1 for Time to Recovery of T4/T1 Ratio to 0.7

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	Hodges-Lehmann and Moses
Median Difference (Final Values) [4]	60.0
95% Confidence Interval	31.0 to 103.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	For the secondary endpoint no equivalence margin was specified (i.e., no formal null-hypothesis was specified); the median difference and associated 95% CI were to further characterize the efficacy of severe renal impaired subjects and controls.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[4]	Other relevant estimation information:
	Estimated median treatment difference (severe renal impairment minus normal renal function) in recovery time (seconds)

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Participants With Severe Renal Impairment	Participants with severe renal impairment will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 PTC. Severe renal impairment was defined as creatinine clearance <30mL/min.
Participants With Normal Renal Function	Participants with normal renal impairment will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 PTC. Normal renal function was defined as creatinine clearance >=80mL/min.

Serious Adverse Events

	Participants With Severe Renal Impairment	Participants With Normal Renal Function
Total, serious adverse events		
# participants affected / at risk	**9/35 (25.71%)**	**3/33 (9.09%)**
Infections and infestations		
Pneumonia [1]		
# participants affected / at risk	**1/35 (2.86%)**	**0/33 (0.00%)**
# events	**1**	**0**
Subdiaphragmatic abscess [1]		
# participants affected / at risk	**0/35 (0.00%)**	**1/33 (3.03%)**
# events	**0**	**1**
Thrombophlebitis septic [1]		
# participants affected / at risk	**1/35 (2.86%)**	**0/33 (0.00%)**
# events	**1**	**0**
Injury, poisoning and procedural complications		
Anastomotic leak [1]		
# participants affected / at risk	**0/35 (0.00%)**	**1/33 (3.03%)**
# events	**0**	**1**
Incision site haematoma [1]		
# participants affected / at risk	**1/35 (2.86%)**	**0/33 (0.00%)**
# events	**1**	**0**
Narcotic intoxication [1]		
# participants affected / at risk	**1/35 (2.86%)**	**0/33 (0.00%)**
# events	**1**	**0**
Seroma [1]		
# participants affected / at risk	**0/35 (0.00%)**	**1/33 (3.03%)**
# events	**0**	**1**
Wound [1]		
# participants affected / at risk	**1/35 (2.86%)**	**0/33 (0.00%)**
# events	**1**	**0**
Wound haemorrhage [1]		
# participants affected / at risk	**2/35 (5.71%)**	**0/33 (0.00%)**
# events	**2**	**0**
Investigations		
Blood creatinine increased [1]		
# participants affected / at risk	**1/35 (2.86%)**	**0/33 (0.00%)**

# events	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Benign ovarian tumour [1]		
# participants affected / at risk	1/35 (2.86%)	0/33 (0.00%)
# events	1	0
Ovarian cancer [1]		
# participants affected / at risk	0/35 (0.00%)	1/33 (3.03%)
# events	0	1
Renal and urinary disorders		
Azotaemia [1]		
# participants affected / at risk	1/35 (2.86%)	0/33 (0.00%)
# events	1	0
Respiratory, thoracic and mediastinal disorders		
Pulmonary oedema [1]		
# participants affected / at risk	1/35 (2.86%)	0/33 (0.00%)
# events	1	0
Respiratory failure [1]		
# participants affected / at risk	1/35 (2.86%)	0/33 (0.00%)
# events	1	0
Vascular disorders		
Extremity necrosis [1]		
# participants affected / at risk	1/35 (2.86%)	0/33 (0.00%)
# events	1	0

1 Term from vocabulary, MedDRA (12.1)

Other Adverse Events

Hide Other Adverse Events

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

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Participants With Severe Renal Impairment	Participants with severe renal impairment will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 PTC. Severe renal impairment was defined as creatinine clearance <30mL/min.
Participants With Normal Renal Function	Participants with normal renal impairment will receive a single bolus dose of 4.0 mg.kg-1 sugammadex at a target depth of blockade of 1-2 PTC. Normal renal function was defined as

	creatinine clearance >=80mL/min.

Other Adverse Events

	Participants With Severe Renal Impairment	Participants With Normal Renal Function
Total, other (not including serious) adverse events		
# participants affected / at risk	**14/35 (40.00%)**	**17/33 (51.52%)**
Blood and lymphatic system disorders		
Anaemia [1]		
# participants affected / at risk	**3/35 (8.57%)**	**0/33 (0.00%)**
# events	**3**	**0**
Gastrointestinal disorders		
Nausea [1]		
# participants affected / at risk	**3/35 (8.57%)**	**0/33 (0.00%)**
# events	**3**	**0**
Vomiting [1]		
# participants affected / at risk	**2/35 (5.71%)**	**0/33 (0.00%)**
# events	**2**	**0**
Injury, poisoning and procedural complications		
Procedural hypertension [1]		
# participants affected / at risk	**0/35 (0.00%)**	**2/33 (6.06%)**
# events	**0**	**2**
Procedural hypotension [1]		
# participants affected / at risk	**4/35 (11.43%)**	**1/33 (3.03%)**
# events	**5**	**1**
Procedural nausea [1]		
# participants affected / at risk	**1/35 (2.86%)**	**3/33 (9.09%)**
# events	**1**	**3**
Procedural pain [1]		
# participants affected / at risk	**9/35 (25.71%)**	**11/33 (33.33%)**
# events	**9**	**13**
Investigations		
Neutrophil count increased [1]		
# participants affected / at risk	**0/35 (0.00%)**	**2/33 (6.06%)**
# events	**0**	**2**
Respiratory, thoracic and mediastinal disorders		
Pneumonia [1]		
# participants affected / at risk	**0/35 (0.00%)**	**2/33 (6.06%)**
# events	**0**	**2**

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

The agreement is:

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

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

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

☑ **Restriction Description:** All published results will be based on validated data released by the sponsor and must include one sponsor author. There may be one author from each investigational site, provided that the criteria for authorship are met. In case the proposed publication contains reference to an invention owned by sponsor or to which sponsor otherwise has rights, the sponsor may request a reasonable suspension of the publication in order to be able to file a patent application protecting such invention.

Results Point of Contact:

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

Publications of Results:

Panhuizen IF, Gold SJ, Buerkle C, Snoeck MM, Harper NJ, Kaspers MJ, van den Heuvel MW, Hollmann MW. Efficacy, safety and pharmacokinetics of sugammadex 4 mg kg-1 for reversal of deep neuromuscular blockade in patients with severe renal impairment. Br J Anaesth. 2015 May;114(5):777-84. doi: 10.1093/bja/aet586. Epub 2015 Mar 31.

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Study First Received:	June 19, 2008
Results First Received:	March 15, 2011
Last Updated:	May 11, 2015
Health Authority:	France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis)

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