Efficacy and Safety of 4.0 mg/kg Sugammadex at 1-2 PTC in Chinese and European Subjects (Study 19.4.335)(P05775AM1)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00826176

First received: January 15, 2009
Last updated: October 6, 2015
Last verified: October 2015
History of Changes

Purpose

The present trial is set up to evaluate the efficacy and safety of 4.0 mg.kg-1 sugammadex in Chinese and Caucasian subjects for registration purposes in China.

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

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

Official Title: A Multi-center, Open Label Trial, to Show Efficacy and Safety of 4.0 mg.Kg-1 Sugammadex Administered at a Depth of Neuromuscular Blockade of 1-2 PTC Induced by Rocuronium in Chinese and European ASA I-III Subjects Undergoing Elective Surgery Under Propofol Anesthesia

Resource links provided by NLM:

MedlinePlus related topics: Anesthesia

Drug Information available for: 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 Sugammadex 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. Analysis of recovery in Chinese subjects was the primary objective; Caucasian subjects and between-group analyses were secondary.

Secondary Outcome Measures:

- Time From Start of Administration of Sugammadex to Recovery of the 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. The greater the T4/T1 ratio the greater the recovery from neuromuscular blockade.

- Time From Start of Administration of Sugammadex 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. The greater the T4/T1 ratio the greater the recovery from neuromuscular blockade.

Enrollment:	164
Study Start Date:	January 2010
Study Completion Date:	August 2010
Primary Completion Date:	August 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Sugammadex in Caucasian Subjects At 1-2 post-tetanic counts (PTC) after the last dose of rocuronium, 4.0 mg.kg-1 sugammadex was to be administered. Caucasian subjects living in Europe.	Drug: Sugammadex After induction of anesthesia an intubation dose of 0.6 mg/kg rocuronium was to be administered. Maintenance doses of 0.1-0.2 mg/kg rocuronium intravenous (IV) could have been administered if necessary. At 1-2 PTC after the last administration of rocuronium, an IV single bolus dose of 4.0 mg/kg sugammadex was to be administered. Other Name: Org 25969, Bridion®
Experimental: Sugammadex in Chinese Subjects At 1-2 post-tetanic counts (PTC) after the last dose of rocuronium, 4.0 mg.kg-1 sugammadex was to be administered. Chinese subjects living in China.	Drug: Sugammadex After induction of anesthesia an intubation dose of 0.6 mg/kg rocuronium was to be administered. Maintenance doses of 0.1-0.2 mg/kg rocuronium intravenous (IV) could have been administered if necessary. At 1-2 PTC after the last administration of rocuronium, an IV single bolus dose of 4.0 mg/kg sugammadex was to be administered. Other Name: Org 25969, Bridion®

Eligibility

Ages Eligible for Study:	18 Years to 64 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

-Subjects who are willing to provide informed consent; be between 18 and 64 years old; are American Society of Anaesthesiology (ASA) class 1-3 (extremes included); scheduled for elective surgery under general anesthesia, allowing stable neuromuscular monitoring, which requires neuromuscular blockade using

rocuronium; be compliant with the dose/visit schedules, and use an accepted method of contraception (if applicable).

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

Exclusion Criteria:

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

(family of) study/sponsor staff.

Contacts and Locations

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

No Contacts or Locations Provided

More Information

Publications:

Yu B, Wang X, Helbo Hansen HS, Huang W-Q, Askeland B, Li S, Ding Z, Abels E, Rietbergen H, Woo T, Pendeville P. Sugammadex 4.0 mg/kg reversal of deep rocuronium-induced neuromuscular blockade: a multicenter study in Chinese and Caucasian patients. J Anesthe Clin Res. 2014;5:408. doi: 10.4172/2155-6148.1000408

Responsible Party:	Merck Sharp & Dohme Corp.
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Other Study ID Numbers:	P05775 19.4.335
Study First Received:	January 15, 2009
Results First Received:	August 9, 2011
Last Updated:	October 6, 2015
Health Authority:	Denmark: Danish Medicines Agency China: Food and Drug Administration

Additional relevant MeSH terms:

Rocuronium	Peripheral Nervous System Agents
Neuromuscular Agents	Pharmacologic Actions
Neuromuscular Blocking Agents	Physiological Effects of Drugs
Neuromuscular Nondepolarizing Agents	

ClinicalTrials.gov processed this record on April 10, 2016

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Results First Received: August 9, 2011

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Anesthesia, General Neuromuscular Blockade
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
Two subjects were screened but not enrolled (one Chinese subject and one Caucasian subject).

Reporting Groups

	Description
Sugammadex in Chinese Subjects	At 1-2 post-tetanic counts (PTC) after the last dose of rocuronium, 4.0 mg.kg-1 sugammadex was to be administered. Chinese subjects living in China.
Sugammadex in Caucasian Subjects	At 1-2 post-tetanic counts (PTC) after the last dose of rocuronium, 4.0 mg.kg-1 sugammadex was to be administered. Caucasian subjects living in Europe.

Participant Flow: Overall Study

	Sugammadex in Chinese Subjects	Sugammadex in Caucasian Subjects
STARTED	**128** [1]	**36** [1]
COMPLETED	**115** [2]	**36** [2]
NOT COMPLETED	**13**	**0**
Lost to Follow-up	**1**	**0**
Subject Withdrew Consent	**3**	**0**
Administrative	**9**	**0**

[1] enrolled
[2] treated and completed

Baseline Characteristics

Hide Baseline Characteristics

Population Description

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

Reporting Groups

	Description
Sugammadex in Chinese Subjects	At 1-2 post-tetanic counts (PTC) after the last dose of rocuronium, 4.0 mg.kg-1 sugammadex was to be administered. Chinese subjects living in China.
Sugammadex in Caucasian Subjects	At 1-2 post-tetanic counts (PTC) after the last dose of rocuronium, 4.0 mg.kg-1 sugammadex was to be administered. Caucasian subjects living in Europe.
Total	Total of all reporting groups

Baseline Measures

	Sugammadex in Chinese Subjects	Sugammadex in Caucasian Subjects	Total
Number of Participants [units: participants]	**115**	**36**	**151**
Age [units: years] Mean (Standard Deviation)	**47.9 (10.0)**	**47.2 (11.0)**	**47.7 (10.2)**
Gender [units: participants]			

Female	**66**	**29**	**95**
Male	**49**	**7**	**56**

Outcome Measures

Hide All Outcome Measures

1. Primary: Time From Start of Administration of Sugammadex 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 From Start of Administration of Sugammadex 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. Analysis of recovery in Chinese subjects was the primary objective; Caucasian subjects and between-group analyses were secondary.
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.
The Full Analysis Set (FAS) consisted of all subjects who received sugammadex and had at least one efficacy measurement. One treated Chinese subject did not have any efficacy data and was thus excluded from the FAS. Hence, 114 Chinese Asian and 36 European Caucasian subjects were included in the FAS.

Reporting Groups

	Description
Sugammadex in Chinese Subjects	At 1-2 post-tetanic counts (PTC) after the last dose of rocuronium, 4.0 mg.kg-1 sugammadex was to be administered. Chinese subjects living in China.
Sugammadex in Caucasian Subjects	At 1-2 post-tetanic counts (PTC) after the last dose of rocuronium, 4.0 mg.kg-1 sugammadex was to be administered. Caucasian subjects living in Europe.

Measured Values

	Sugammadex in Chinese Subjects	**Sugammadex in Caucasian Subjects**
Number of Participants Analyzed [units: participants]	**114**	**36**
Time From Start of Administration of Sugammadex to Recovery of the T4/T1 Ratio to 0.9 [units: minutes] Geometric Mean (95% Confidence Interval)	**2.3 (2.1 to 2.6)**	**1.4 (1.3 to 1.6)**

Statistical Analysis 1 for Time From Start of Administration of Sugammadex to Recovery of the T4/T1 Ratio to 0.9

Groups [1]	Sugammadex in Chinese Subjects

upper limit of tolerance interval (min.) [2]	6.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	The tolerance interval (TI) refers to a fixed proportion (in this trial set to 95%) of the population with a stated confidence (in this trial, 95%). Efficacy was to be claimed in case the upper limit of TI was below the prespecified margin of 10 min.

Statistical Analysis 2 for Time From Start of Administration of Sugammadex to Recovery of the T4/T1 Ratio to 0.9

Groups [1]	Sugammadex in Caucasian Subjects
upper limit of tolerance interval (min.) [2]	3.2

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	The tolerance interval (TI) refers to a fixed proportion (in this trial set to 95%) of the population with a stated confidence (in this trial, 95%). Efficacy was to be claimed in case the upper limit of TI was below the prespecified margin of 10 min.

Statistical Analysis 3 for Time From Start of Administration of Sugammadex to Recovery of the T4/T1 Ratio to 0.9

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
median difference (seconds) [3]	49
95% Confidence Interval	30 to 72

[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:
	Equivalence between the two subject populations was to be claimed in the event that the two-sided 95% confidence interval was entirely within the interval ranging from -60 to +60 seconds.
[3]	Other relevant estimation information:
	The estimated median difference (Chinese minus Caucasian) in time to recovery of the T4/T1 ratio to 0.9.

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

Measure Type	Secondary
Measure Title	Time From Start of Administration of Sugammadex to Recovery of the 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. The greater the T4/T1 ratio the greater the recovery from neuromuscular blockade.
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.
The Full Analysis Set (FAS) consisted of all subjects who received sugammadex and had at least one efficacy measurement. One treated Chinese subject did not have any efficacy data and was thus excluded from the FAS. Hence, 114 Chinese Asian and 36 European Caucasian subjects were included in the FAS.

Reporting Groups

	Description
Sugammadex in Chinese Subjects	At 1-2 post-tetanic counts (PTC) after the last dose of rocuronium, 4.0 mg.kg-1 sugammadex was to be administered. Chinese subjects living in China.
Sugammadex in Caucasian Subjects	At 1-2 post-tetanic counts (PTC) after the last dose of rocuronium, 4.0 mg.kg-1 sugammadex was to be administered. Caucasian subjects living in Europe.

Measured Values

	Sugammadex in Chinese Subjects	**Sugammadex in Caucasian Subjects**
Number of Participants Analyzed [units: participants]	**114**	**36**
Time From Start of Administration of Sugammadex to Recovery of the T4/T1 Ratio to 0.7 [units: minutes] Geometric Mean (95% Confidence Interval)	**1.6 (1.5 to 1.8)**	**1.1 (1.0 to 1.2)**

No statistical analysis provided for Time From Start of Administration of Sugammadex to Recovery of the T4/T1 Ratio to 0.7

3. Secondary: Time From Start of Administration of Sugammadex 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 From Start of Administration of Sugammadex 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. The greater the T4/T1 ratio the greater the recovery from neuromuscular blockade.
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.
The Full Analysis Set (FAS) consisted of all subjects who received sugammadex and had at least one efficacy measurement. One treated Chinese subject did not have any efficacy data and was thus excluded from the FAS. Hence, 114 Chinese Asian and 36 European Caucasian subjects were included in the FAS.

Reporting Groups

	Description
Sugammadex in Chinese Subjects	At 1-2 post-tetanic counts (PTC) after the last dose of rocuronium, 4.0 mg.kg-1 sugammadex was to be administered. Chinese subjects living in China.
Sugammadex in Caucasian Subjects	At 1-2 post-tetanic counts (PTC) after the last dose of rocuronium, 4.0 mg.kg-1 sugammadex was to be administered. Caucasian subjects living in Europe.

Measured Values

	Sugammadex in Chinese Subjects	Sugammadex in Caucasian Subjects
Number of Participants Analyzed [units: participants]	**114**	**36**
Time From Start of Administration of Sugammadex to Recovery of the T4/T1 Ratio to 0.8 [units: minutes] Geometric Mean (95% Confidence Interval)	**1.9 (1.7 to 2.1)**	**1.2 (1.1 to 1.3)**

No statistical analysis provided for Time From Start of Administration of Sugammadex to Recovery of the T4/T1 Ratio to 0.8

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Sugammadex in Chinese Subjects	At 1-2 post-tetanic counts (PTC) after the last dose of rocuronium, 4.0 mg.kg-1 sugammadex was to be administered. Chinese subjects living in China.
Sugammadex in Caucasian Subjects	At 1-2 post-tetanic counts (PTC) after the last dose of rocuronium, 4.0 mg.kg-1 sugammadex was to be administered. Caucasian subjects living in Europe.

Serious Adverse Events

	Sugammadex in Chinese Subjects	Sugammadex in Caucasian Subjects
Total, serious adverse events		
# participants affected / at risk	**0/115 (0.00%)**	**1/36 (2.78%)**
Injury, poisoning and procedural complications		
post procedural haemorrhage [1]		
# participants affected / at risk	**0/115 (0.00%)**	**1/36 (2.78%)**
# events	**0**	**1**

1 Term from vocabulary, MedDRA (13.1)

Other Adverse Events

Hide Other Adverse Events

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

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Sugammadex in Chinese Subjects	At 1-2 post-tetanic counts (PTC) after the last dose of rocuronium, 4.0 mg.kg-1 sugammadex was to be administered. Chinese subjects living in China.
Sugammadex in Caucasian Subjects	At 1-2 post-tetanic counts (PTC) after the last dose of rocuronium, 4.0 mg.kg-1 sugammadex was to be administered. Caucasian subjects living in Europe.

Other Adverse Events

	Sugammadex in Chinese Subjects	Sugammadex in Caucasian Subjects
Total, other (not including serious) adverse events		
# participants affected / at risk	**46/115 (40.00%)**	**20/36 (55.56%)**
Gastrointestinal disorders		
abdominal pain [1]		
# participants affected / at risk	**1/115 (0.87%)**	**6/36 (16.67%)**
# events	**1**	**9**
abdominal pain lower [1]		
# participants affected / at risk	**0/115 (0.00%)**	**6/36 (16.67%)**
# events	**0**	**10**
nausea [1]		
# participants affected / at risk	**8/115 (6.96%)**	**7/36 (19.44%)**
# events	**8**	**10**
vomiting [1]		
# participants affected / at risk	**12/115 (10.43%)**	**5/36 (13.89%)**
# events	**12**	**5**
General disorders		
instillation site erythema [1]		
# participants affected / at risk	**0/115 (0.00%)**	**2/36 (5.56%)**
# events	**0**	**2**
Injury, poisoning and procedural complications		
incision site pain [1]		
# participants affected / at risk	**26/115 (22.61%)**	**1/36 (2.78%)**

# events	26	1
procedural hypotension [1]		
# participants affected / at risk	3/115 (2.61%)	6/36 (16.67%)
# events	3	10
wound complication [1]		
# participants affected / at risk	0/115 (0.00%)	3/36 (8.33%)
# events	0	7
Nervous system disorders		
dizziness [1]		
# participants affected / at risk	3/115 (2.61%)	5/36 (13.89%)
# events	3	8
Respiratory, thoracic and mediastinal disorders		
cough [1]		
# participants affected / at risk	9/115 (7.83%)	1/36 (2.78%)
# events	9	1
rhinalgia [1]		
# participants affected / at risk	0/115 (0.00%)	3/36 (8.33%)
# events	0	3

1 Term from vocabulary, MedDRA (13.1)

Limitations and Caveats

Hide Limitations and Caveats

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

No text entered.

More Information

Hide More Information

Certain Agreements:

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

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

The agreement is:

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

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

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

☑ **Restriction Description:** Investigator may not publish/publicly present interim results without prior consent of Sponsor. Any materials that report results of the study must be sent to Sponsor 45 days prior to submission for publication/presentation. Sponsor has right to review and comment. In case of any disagreements concerning appropriateness of the materials, investigator and Sponsor must meet to make

a good faith effort to discuss/resolve the issues or disagreement, prior to submission for publication/presentation.

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:

Yu B, Wang X, Helbo Hansen HS, Huang W-Q, Askeland B, Li S, Ding Z, Abels E, Rietbergen H, Woo T, Pendeville P. Sugammadex 4.0 mg/kg reversal of deep rocuronium-induced neuromuscular blockade: a multicenter study in Chinese and Caucasian patients. J Anesthe Clin Res. 2014;5:408. doi: 10.4172/2155-6148.1000408

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