Dialysis of Sugammadex in Participants With Severe Renal Impairment (Study 19.4.333) (P05773)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00656799

First received: April 7, 2008
Last updated: February 20, 2015
Last verified: February 2015
History of Changes

Purpose

The clinical trial objectives were to evaluate the dialysability of the sugammadex-rocuronium complex; it's safety and efficacy in participants with severe renal impairment.

Condition	Intervention	Phase
Neuromuscular Blockade	Drug: sugammadex Drug: Rocuronium	Phase 3

Study Type: Interventional
Study Design: Endpoint Classification: Pharmacokinetics Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Single Center, Open-Label Trial in Subjects With Severe Renal Impairment Evaluating the Dialysability of the Sugammadex-Rocuronium Complex

Resource links provided by NLM:

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:

- Clearance of Sugammadex by Dialysis as Measured by the Reduction Ratio (RR) [Time Frame: Up to day 7] [Designated as safety issue: No]

  Starting on Day 1 dialysis was performed on four separate occasions using a Fresenius 40008H hemodialyzer, with a hemodiafilter standard helixone membrane FX 600. Dialysate samples were collected before, and after hemodialysis, with concentrations of sugammadex determined

using a liquid chromatographic assay with mass spectrometric detection. The clearance of sugammadex at each dialysis session was calculated by measuring the ratio of plasma concentration at the end of dialysis, average duration of 6 hours, compared with that immediately before the start of dialysis, called the RR.

- Clearance of Rocuronium by Dialysis as Measured by the Reduction Ratio (RR) [Time Frame: Up to Day 7] [Designated as safety issue: No]

  Starting on Day 1 dialysis was performed on four separate occasions using a Fresenius 40008H hemodialyzer, with a hemodiafilter standard helixone membrane FX 600. Dialysate samples were collected before, and after hemodialysis, with concentrations of rocuronium determined using a liquid chromatographic assay with mass spectrometric detection. The clearance of rocuronium at each dialysis session was calculated by measuring the ratio of plasma concentration at the end of dialysis, average duration of 6 hours, compared with that immediately before the start of dialysis, called the RR.

- Rate of Clearance of Sugammadex From Blood [Time Frame: Up to day 7] [Designated as safety issue: No]

  Starting on Day 1 dialysis was performed on four separate occasions using a Fresenius 40008H hemodialyzer, with a hemodiafilter standard helixone membrane FX 600. Blood samples were collected from ports in the arterial and venous tubing of the dialyzer before, during and after an average of 6 hours of hemodialysis. The concentrations of sugammadex were determined using a liquid chromatographic assay with mass spectrometric detection. The clearance rate from blood at each dialysis session was assessed by averaging across all available collection time points.

- Rate of Clearance of Rocuronium From Blood [Time Frame: Up to Day 7] [Designated as safety issue: No]

  Starting on Day 1 dialysis was performed on four separate occasions using a Fresenius 40008H hemodialyzer, with a hemodiafilter standard helixone membrane FX 600. Blood samples were collected from ports in the arterial and venous tubing of the dialyzer before, during and after an average of 6 hours of hemodialysis. The concentrations of rocuronium were determined using a liquid chromatographic assay with mass spectrometric detection. The clearance rate from blood at each dialysis session was assessed by averaging across all available collection time points.

- Rate of Clearance of Sugammadex From Dialysate [Time Frame: Up to day 7] [Designated as safety issue: No]

  Starting on Day 1 dialysis was performed on four separate occasions using a Fresenius 40008H hemodialyzer, with a hemodiafilter standard helixone membrane FX 600. Dialysate samples were collected from a port in the outflow of the dialyzer before, during and after an average of 6 hours of hemodialysis. The concentrations of sugammadex were determined using a liquid chromatographic assay with mass spectrometric detection. The clearance rate from dialysate at each dialysis session was assessed by averaging across all available collection time points.The data from the fourth dialysis are not presented as they were not calculable.

- Rate of Clearance of Rocuronium From Dialysate [Time Frame: Up to Day 7] [Designated as safety issue: No]

  Starting on Day 1 dialysis was performed on four separate occasions using a Fresenius 40008H hemodialyzer, with a hemodiafilter standard helixone membrane FX 600. Dialysate samples were collected from a port in the outflow of the dialyzer before, during and after an average of 6 hours of hemodialysis. The concentrations of rocuronium were determined using a liquid chromatographic assay with mass spectrometric detection. The clearance rate from dialysate at each dialysis session was assessed by averaging across all available collection time points.

Secondary Outcome Measures:

- Number of Participants With Pre-treatment Adverse Events (AEs) [Time Frame: Screening up to Day 1] [Designated as safety issue: Yes]

  An AE is any unfavorable and unintended change in the structure, function or chemistry of the body, whether or not related to the use of a product.

- Number of Participants With Serious Adverse Events (SAEs) [Time Frame: Up to day 7] [Designated as safety issue: Yes]

  A SAE is any untoward medical occurrence that at any dose results in the following: death, is life threatening, requires in-patient hospitalization or prolongation of existing hospitalization, persistent or significant disability/incapacity, or is a congenital anomaly/birth defect

- Number of Participants With Medical Device (Near) Incidents [Time Frame: Up to day 7] [Designated as safety issue: Yes]

  A medical device (near) incident is defined as an occurrence due to inaccurate or inadequate labeling/instructions, or information supplied with a medical device; or malfunction, deterioration or recall of a medical device that could lead to death or serious deterioration in health.

- Vital Sign: Mean Systolic Blood Pressure [Time Frame: Screening up to 1 day after surgery] [Designated as safety issue: Yes]

  Systolic blood pressure was measured at the following time points: screening, before rocuronium treatment, before sugammadex treatment, at 2, 5, 10, 20 minutes post-sugammadex treatment, and the day after surgery

- Vital Sign: Mean Diastolic Blood Pressure [Time Frame: Screening up to 1 day after surgery] [Designated as safety issue: Yes]

Diastolic blood pressure was measured at the following time points: screening, before rocuronium treatment, before sugammadex treatment, at 2, 5, 10, 20 minutes post-sugammadex treatment, and the day after surgery

- Vital Sign: Mean Heart Rate [Time Frame: Screening up to 1 day after surgery] [Designated as safety issue: Yes]

  Heart rate was measured at the following time points: screening, before rocuronium treatment, before sugammadex treatment, at 2, 5, 10, 20 minutes post-sugammadex treatment, and the day after surgery

- Number of Participants With Physical Examinations [Time Frame: Screening up to day 7] [Designated as safety issue: Yes]

  Physical examinations were to be conducted at screening, on Day 1 and 7 days after surgery

- Number of Participants With Reoccurrence of Neuromuscular Blockade at Day 1 [Time Frame: Day 1] [Designated as safety issue: Yes]

  Neuromuscular function was monitored by applying repetitive train of four (TOF) electrical stimulations to the ulnar nerve every 15 seconds and assessing the magnitudes (heights) of the first twitch (T1) and fourth twitch (T4) response at the adductor pollicis muscle with a TOF-Watch® SX. Stimulation continued until the T4/T1 ratio reached at least 0.9. Higher T4/T1 ratios represent greater recovery from neuromuscular blockade; with a value of 1.0 representing full recovery. Reoccurrence of neuromuscular blockade is defined as a decline in the T4/T1 ratio from >= 0.9 to < 0.8 in at least three consecutive measurements.

- Number of Participants With Events Due to Possible Interaction of Sugammadex With Endo-/Exogenous Compounds Other Than Rocuronium [Time Frame: Day 1] [Designated as safety issue: Yes]

  Evidence of AEs due to possible interaction of sugammadex with endogenous compounds or with exogenous compounds other than rocuronium

- Number of Participants With Pregnancies at 30 Days Post-dose [Time Frame: Up to 30 days post -dose] [Designated as safety issue: Yes]

  Pregnancies reported by means of a Pregnancy Reporting Form, consist of pregnant female participants or pregnant female partners of male participants

- Time From Start of Administration of Sugammadex to Recovery of T4/T1 Ratio to 0.9 [Time Frame: Day 1] [Designated as safety issue: No]

  Neuromuscular function was monitored by applying repetitive train of four (TOF) electrical stimulations to the ulnar nerve every 15 seconds and assessing the magnitudes (heights) of the first twitch (T1) and fourth twitch (T4) response at the adductor pollicis muscle with a TOF-Watch® SX. Stimulation continued until the T4/T1 ratio reached at least 0.9. Higher T4/T1 ratios represent greater recovery from neuromuscular blockade; with a value of 1.0 representing full recovery.

- Time From Start of Administration of Sugammadex to Recovery of T4/T1 Ratio to 0.8 [Time Frame: Day 1] [Designated as safety issue: No]

  Neuromuscular function was monitored by applying repetitive TOF electrical stimulations to the ulnar nerve every 15 seconds and assessing the magnitudes (heights) of the T1 and T4 response at the adductor pollicis muscle with a TOF-Watch® SX. Stimulation continued until the T4/T1 ratio reached at least 0.8. Higher T4/T1 ratios represent greater recovery from neuromuscular blockade; with a value of 1.0 representing full recovery.

- Time From Start of Administration of Sugammadex to Recovery of T4/T1 Ratio to 0.7 [Time Frame: Day 1] [Designated as safety issue: No]

  Neuromuscular function was monitored by applying repetitive TOF electrical stimulations to the ulnar nerve every 15 seconds and assessing the magnitudes (heights) of the T1 and T4 response at the adductor pollicis muscle with a TOF-Watch® SX. Stimulation continued until the T4/T1 ratio reached at least 0.7. Higher T4/T1 ratios represent greater recovery from neuromuscular blockade; with a value of 1.0 representing full recovery.

Enrollment:	6
Study Start Date:	April 2008
Study Completion Date:	July 2009
Primary Completion Date:	July 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Sugammadex IV single bolus dose of 4.0 mg/kg sugammadex	Drug: sugammadex At 15 minutes after administration of rocuronium, an IV single bolus dose of 4.0 mg/kg sugammadex was administered. Other Names: • Org 25969

	• SCH 900616 • MK-8616 • Bridion® Drug: Rocuronium After achieving stable anesthesia an IV single bolus dose of 0.6 mg/kg rocuronium was administered Other Names: • Rocuronium bromide • Esmeron®

Detailed Description:

The current trial was designed to evaluate the dialysability of the sugammadex-rocuronium complex in participants with severe renal impairment. A dose of 4.0 mg/kg sugammadex was administered 15 minutes after administration of 0.6 mg/kg rocuronium. Blood and dialysate samples were collected before, during and after hemodialysis/filtration, for calculation of clearance of sugammadex-rocuronium complex and assessment of rebound.

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
- American Society of Anesthesiologists (ASA) Class >=4
- Creatinine clearance (CLCR) < 30 mL/min and clinical indication for dialysis
- Hospitalization at Intensive Care Unit (ICU) and scheduled for a (surgical) procedure under general anesthesia requiring neuromuscular relaxation with the use of rocuronium
- Scheduled for a (surgical) procedure in supine position
- Written informed consent (of the legal representative)

Exclusion Criteria:

- Known or suspected to have neuromuscular disorders impairing neuromuscular blockade and/or significant hepatic dysfunction
- Known or suspected to have a (family) history of malignant hyperthermia
- Known or suspected to have an allergy to narcotics, muscle relaxants or other medication used during general anesthesia
- Have already participated in a sugammadex trial
- Have participated in another clinical trial, not preapproved by NV Organon, within 30 days of study entry
- Females who are pregnant*
- Females who are breast-feeding * In females pregnancy will be excluded both from medical history and by a human chorionic gonadotropin (hCG) test within 24 hours before surgery except in females who are not of childbearing potential, i.e. at least 2 years menopausal or have undergone tubal ligation or an hysterectomy.

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:

Cammu G, Van Vlem B, van den Heuvel M, Stet L, el Galta R, Eloot S, Demeyer I. Dialysability of sugammadex and its complex with rocuronium in

intensive care patients with severe renal impairment. Br J Anaesth. 2012 Sep;109(3):382-90. doi: 10.1093/bja/aes207. Epub 2012 Jun 24.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00656799 History of Changes
Other Study ID Numbers:	P05773 2007-006934-33
Study First Received:	April 7, 2008
Results First Received:	May 21, 2013
Last Updated:	February 20, 2015
Health Authority:	Belgium: Federal Agency for Medicinal Products and Health Products

Additional relevant MeSH terms:

- Renal Insufficiency
- Kidney Diseases
- Urologic Diseases
- Rocuronium
- Neuromuscular Agents
- Neuromuscular Blocking Agents
- Neuromuscular Nondepolarizing Agents
- Peripheral Nervous System Agents
- Pharmacologic Actions
- Physiological Effects of Drugs

ClinicalTrials.gov processed this record on April 10, 2016

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NCT00656799

First received: April 7, 2008
Last updated: February 20, 2015
Last verified: February 2015
History of Changes

Results First Received: May 21, 2013

Study Type:	Interventional
Study Design:	Endpoint Classification: Pharmacokinetics Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Neuromuscular Blockade
Interventions:	Drug: sugammadex Drug: Rocuronium

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
Sugammadex	

	Intravenous (IV) single bolus dose of 4.0 mg/kg sugammadex

Participant Flow: Overall Study

	Sugammadex
STARTED	6
COMPLETED	4
NOT COMPLETED	2
Death	2

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	IV single bolus dose of 4.0 mg/kg sugammadex

Baseline Measures

	Sugammadex
Number of Participants [units: participants]	6
Age [units: years] Mean (Standard Deviation)	76 (7)
Gender [units: participants]	
Female	2
Male	4

Outcome Measures

Hide All Outcome Measures

1. Primary: Clearance of Sugammadex by Dialysis as Measured by the Reduction Ratio (RR) [Time Frame: Up to day 7]

Measure Type	Primary
Measure Title	Clearance of Sugammadex by Dialysis as Measured by the Reduction Ratio (RR)

Measure Description	Starting on Day 1 dialysis was performed on four separate occasions using a Fresenius 40008H hemodialyzer, with a hemodiafilter standard helixone membrane FX 600. Dialysate samples were collected before, and after hemodialysis, with concentrations of sugammadex determined using a liquid chromatographic assay with mass spectrometric detection. The clearance of sugammadex at each dialysis session was calculated by measuring the ratio of plasma concentration at the end of dialysis, average duration of 6 hours, compared with that immediately before the start of dialysis, called the RR.
Time Frame	Up to day 7
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.
All subjects pharmacokinetically evaluable consisting of all participants who received a dose of sugammadex and had at least one efficacy measurement

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed [units: participants]	**6**
Clearance of Sugammadex by Dialysis as Measured by the Reduction Ratio (RR) [units: Reduction Ratio] Mean (Standard Deviation)	
First Dialysis (n=5)	**0.687 (0.113)**
Second Dialysis (n=6)	**0.566 (0.150)**
Third Dialysis (n=4)	**0.516 (0.232)**
Fourth Dialysis (n=4)	**0.532 (0.144)**

No statistical analysis provided for Clearance of Sugammadex by Dialysis as Measured by the Reduction Ratio (RR)

2. Primary: Clearance of Rocuronium by Dialysis as Measured by the Reduction Ratio (RR) [Time Frame: Up to Day 7]

Measure Type	Primary
Measure Title	Clearance of Rocuronium by Dialysis as Measured by the Reduction Ratio (RR)
Measure Description	Starting on Day 1 dialysis was performed on four separate occasions using a Fresenius 40008H hemodialyzer, with a hemodiafilter standard helixone membrane FX 600. Dialysate samples were collected before, and after hemodialysis, with concentrations of rocuronium determined using a liquid chromatographic assay with mass spectrometric detection. The clearance of rocuronium at each dialysis session was calculated by measuring the ratio of plasma concentration at

	the end of dialysis, average duration of 6 hours, compared with that immediately before the start of dialysis, called the RR.
Time Frame	Up to Day 7
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.
All subjects pharmacokinetically evaluable consisting of all participants who received a dose of sugammadex and had at least one efficacy measurement

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed [units: participants]	**6**
Clearance of Rocuronium by Dialysis as Measured by the Reduction Ratio (RR) [units: Reduction Ratio] Mean (Standard Deviation)	
First Dialysis (n=5)	**0.750 (0.0786)**
Second Dialysis (n=6)	**0.625 (0.144)**
Third Dialysis (n=4)	**0.521 (0.0489)**
Fourth Dialysis (n=4)	**0.458 (0.115)**

No statistical analysis provided for Clearance of Rocuronium by Dialysis as Measured by the Reduction Ratio (RR)

3. Primary: Rate of Clearance of Sugammadex From Blood [Time Frame: Up to day 7]

Measure Type	Primary
Measure Title	Rate of Clearance of Sugammadex From Blood
Measure Description	Starting on Day 1 dialysis was performed on four separate occasions using a Fresenius 40008H hemodialyzer, with a hemodiafilter standard helixone membrane FX 600. Blood samples were collected from ports in the arterial and venous tubing of the dialyzer before, during and after an average of 6 hours of hemodialysis. The concentrations of sugammadex were determined using a liquid chromatographic assay with mass spectrometric detection. The clearance rate from blood at each dialysis session was assessed by averaging across all available collection time points.
Time Frame	Up to day 7
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.
All subjects pharmacokinetically evaluable consisting of all participants who received a dose of sugammadex and had at least one efficacy measurement

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed [units: participants]	**6**
Rate of Clearance of Sugammadex From Blood [units: mL/min] Mean (Standard Deviation)	
First Dialysis (n=5)	**79.1 (19.0)**
Second Dialysis (n=6)	**76.5 (19.6)**
Third Dialysis (n=4)	**72.4 (18.4)**
Fourth Dialysis (n=4)	**83.4 (16.5)**

No statistical analysis provided for Rate of Clearance of Sugammadex From Blood

4. Primary: Rate of Clearance of Rocuronium From Blood [Time Frame: Up to Day 7]

Measure Type	Primary
Measure Title	Rate of Clearance of Rocuronium From Blood
Measure Description	Starting on Day 1 dialysis was performed on four separate occasions using a Fresenius 40008H hemodialyzer, with a hemodiafilter standard helixone membrane FX 600. Blood samples were collected from ports in the arterial and venous tubing of the dialyzer before, during and after an average of 6 hours of hemodialysis. The concentrations of rocuronium were determined using a liquid chromatographic assay with mass spectrometric detection. The clearance rate from blood at each dialysis session was assessed by averaging across all available collection time points.
Time Frame	Up to Day 7
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.
All subjects pharmacokinetically evaluable consisting of all participants who received a dose of sugammadex and had at least one efficacy measurement

Reporting Groups

	Description

Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed [units: participants]	**6**
Rate of Clearance of Rocuronium From Blood [units: mL/min] Mean (Standard Deviation)	
First Dialysis (n=5)	**80.2 (15.2)**
Second Dialysis (n=6)	**86.3 (14.1)**
Third Dialysis (n=4)	**94.1 (14.8)**
Fourth Dialysis (n=3)	**94.8 (9.68)**

No statistical analysis provided for Rate of Clearance of Rocuronium From Blood

5. Primary: Rate of Clearance of Sugammadex From Dialysate [Time Frame: Up to day 7]

Measure Type	Primary
Measure Title	Rate of Clearance of Sugammadex From Dialysate
Measure Description	Starting on Day 1 dialysis was performed on four separate occasions using a Fresenius 40008H hemodialyzer, with a hemodiafilter standard helixone membrane FX 600. Dialysate samples were collected from a port in the outflow of the dialyzer before, during and after an average of 6 hours of hemodialysis. The concentrations of sugammadex were determined using a liquid chromatographic assay with mass spectrometric detection. The clearance rate from dialysate at each dialysis session was assessed by averaging across all available collection time points.The data from the fourth dialysis are not presented as they were not calculable.
Time Frame	Up to day 7
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.
All subjects pharmacokinetically evaluable consisting of all participants who received a dose of sugammadex and had at least one efficacy measurement

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed	

[units: participants]	**6**
Rate of Clearance of Sugammadex From Dialysate **[units: mL/min]** **Mean (Standard Deviation)**	
First Dialysis (n=5)	**63.0 (8.74)**
Second Dialysis (n=6)	**65.1 (7.06)**
Third Dialysis (n=4)	**66.8 (13.2)**

No statistical analysis provided for Rate of Clearance of Sugammadex From Dialysate

6. Primary: Rate of Clearance of Rocuronium From Dialysate [Time Frame: Up to Day 7]

Measure Type	Primary
Measure Title	Rate of Clearance of Rocuronium From Dialysate
Measure Description	Starting on Day 1 dialysis was performed on four separate occasions using a Fresenius 40008H hemodialyzer, with a hemodiafilter standard helixone membrane FX 600. Dialysate samples were collected from a port in the outflow of the dialyzer before, during and after an average of 6 hours of hemodialysis. The concentrations of rocuronium were determined using a liquid chromatographic assay with mass spectrometric detection. The clearance rate from dialysate at each dialysis session was assessed by averaging across all available collection time points.
Time Frame	Up to Day 7
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.
All subjects pharmacokinetically evaluable consisting of all participants who received a dose of sugammadex and had at least one efficacy measurement

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed **[units: participants]**	**6**
Rate of Clearance of Rocuronium From Dialysate **[units: mL/min]** **Mean (Standard Deviation)**	
First Dialysis (n=5)	**75.1 (5.81)**
Second Dialysis (n=6)	**97.2 (32.4)**
Third Dialysis (n=4)	**110 (36.4)**

Fourth Dialysis (n=4)	**95.3 (19.2)**

No statistical analysis provided for Rate of Clearance of Rocuronium From Dialysate

7. Secondary: Number of Participants With Pre-treatment Adverse Events (AEs) [Time Frame: Screening up to Day 1]

Measure Type	Secondary
Measure Title	Number of Participants With Pre-treatment Adverse Events (AEs)
Measure Description	An AE is any unfavorable and unintended change in the structure, function or chemistry of the body, whether or not related to the use of a product.
Time Frame	Screening up to Day 1
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.
All Subjects Treated (AST) consisting of participants who received a dose of sugammadex

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed [units: participants]	**6**
Number of Participants With Pre-treatment Adverse Events (AEs) [units: participants]	**1**

No statistical analysis provided for Number of Participants With Pre-treatment Adverse Events (AEs)

8. Secondary: Number of Participants With Serious Adverse Events (SAEs) [Time Frame: Up to day 7]

Measure Type	Secondary
Measure Title	Number of Participants With Serious Adverse Events (SAEs)
Measure Description	A SAE is any untoward medical occurrence that at any dose results in the following: death, is life threatening, requires in-patient hospitalization or prolongation of existing hospitalization, persistent or significant disability/incapacity, or is a congenital anomaly/birth defect
Time Frame	Up to day 7
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.
AST consisting of all participants who received a dose of sugammadex

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed [units: participants]	**6**
Number of Participants With Serious Adverse Events (SAEs) [units: participants]	**2**

No statistical analysis provided for Number of Participants With Serious Adverse Events (SAEs)

9. Secondary: Number of Participants With Medical Device (Near) Incidents [Time Frame: Up to day 7]

Measure Type	Secondary
Measure Title	Number of Participants With Medical Device (Near) Incidents
Measure Description	A medical device (near) incident is defined as an occurrence due to inaccurate or inadequate labeling/instructions, or information supplied with a medical device; or malfunction, deterioration or recall of a medical device that could lead to death or serious deterioration in health.
Time Frame	Up to day 7
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.
AST consisting of all participants who received a dose of sugammadex

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed [units: participants]	**6**

Number of Participants With Medical Device (Near) Incidents [units: participants]	0

No statistical analysis provided for Number of Participants With Medical Device (Near) Incidents

10. Secondary: Vital Sign: Mean Systolic Blood Pressure [Time Frame: Screening up to 1 day after surgery]

Measure Type	Secondary
Measure Title	Vital Sign: Mean Systolic Blood Pressure
Measure Description	Systolic blood pressure was measured at the following time points: screening, before rocuronium treatment, before sugammadex treatment, at 2, 5, 10, 20 minutes post-sugammadex treatment, and the day after surgery
Time Frame	Screening up to 1 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.
AST consisting of all participants who received a dose of sugammadex

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed [units: participants]	**6**
Vital Sign: Mean Systolic Blood Pressure [units: mm Hg] Mean (Standard Deviation)	
Screening	**124.2 (19.2)**
Pre-Rocuronium	**106.3 (25.2)**
Baseline pre-sugammadex	**105.5 (20.4)**
2 minutes post-sugammadex	**105.0 (11.5)**
5 minutes post-sugammadex	**103.2 (10.0)**
10 minutes post-sugammadex	**98.0 (10.9)**
30 minutes post-sugammadx	**92.8 (21.3)**
Post-anesthetic	**146.3 (26.7)**

No statistical analysis provided for Vital Sign: Mean Systolic Blood Pressure

11. Secondary: Vital Sign: Mean Diastolic Blood Pressure [Time Frame: Screening up to 1 day after surgery]

Measure Type	Secondary
Measure Title	Vital Sign: Mean Diastolic Blood Pressure
Measure Description	Diastolic blood pressure was measured at the following time points: screening, before rocuronium treatment, before sugammadex treatment, at 2, 5, 10, 20 minutes post-sugammadex treatment, and the day after surgery
Time Frame	Screening up to 1 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.
AST consisting of all participants who received a dose of sugammadex

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed [units: participants]	**6**
Vital Sign: Mean Diastolic Blood Pressure [units: mm Hg] Mean (Standard Deviation)	
Screening	**58.2 (6.2)**
Pre-Rocuronium	**51.2 (13.6)**
Baseline pre-sugammadex	**45.2 (13.3)**
2 minutes post-sugammadex	**46.5 (12.3)**
5 minutes post-sugammadex	**44.5 (12.1)**
10 minutes post-sugammadex	**46.8 (8.9)**
30 minutes post-sugammadex	**43.7 (9.4)**
Post-anesthetic	**67.8 (13.2)**

No statistical analysis provided for Vital Sign: Mean Diastolic Blood Pressure

12. Secondary: Vital Sign: Mean Heart Rate [Time Frame: Screening up to 1 day after surgery]

Measure Type	Secondary
Measure Title	

	Vital Sign: Mean Heart Rate
Measure Description	Heart rate was measured at the following time points: screening, before rocuronium treatment, before sugammadex treatment, at 2, 5, 10, 20 minutes post-sugammadex treatment, and the day after surgery
Time Frame	Screening up to 1 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.
AST consisting of all participants who received a dose of sugammadex

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed [units: participants]	**6**
Vital Sign: Mean Heart Rate [units: Beats per minute] Mean (Standard Deviation)	
Screening	**81.7 (22.6)**
Pre-Rocuronium	**78.0 (21.4)**
Baseline pre-sugammadex	**83.7 (21.4)**
2 minutes post-sugammadex	**81.0 (20.8)**
5 minutes post-sugammadex	**80.5 (20.4)**
10 minutes post-sugammadex	**80.2 (20.4)**
30 minutes post-sugammadex	**77.8 (20.1)**
Post-anesthetic	**71.8 (11.1)**

No statistical analysis provided for Vital Sign: Mean Heart Rate

13. Secondary: Number of Participants With Physical Examinations [Time Frame: Screening up to day 7]

Measure Type	Secondary
Measure Title	Number of Participants With Physical Examinations
Measure Description	Physical examinations were to be conducted at screening, on Day 1 and 7 days after surgery
Time Frame	Screening up to day 7
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.
AST consisting of all participants who received a dose of sugammadex

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed [units: participants]	**6**
Number of Participants With Physical Examinations [units: participants]	
Screening	**6**
Peri-procedural (Day 1)	**6**
Day 7	**0**

No statistical analysis provided for Number of Participants With Physical Examinations

14. Secondary: Number of Participants With Reoccurrence of Neuromuscular Blockade at Day 1 [Time Frame: Day 1]

Measure Type	Secondary
Measure Title	Number of Participants With Reoccurrence of Neuromuscular Blockade at Day 1
Measure Description	Neuromuscular function was monitored by applying repetitive train of four (TOF) electrical stimulations to the ulnar nerve every 15 seconds and assessing the magnitudes (heights) of the first twitch (T1) and fourth twitch (T4) response at the adductor pollicis muscle with a TOF-Watch® SX. Stimulation continued until the T4/T1 ratio reached at least 0.9. Higher T4/T1 ratios represent greater recovery from neuromuscular blockade; with a value of 1.0 representing full recovery. Reoccurrence of neuromuscular blockade is defined as a decline in the T4/T1 ratio from >= 0.9 to < 0.8 in at least three consecutive measurements.
Time Frame	Day 1
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.
AST consisting of all screened participants who received a dose of sugammadex

Reporting Groups

	Description

Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed [units: participants]	**6**
Number of Participants With Reoccurrence of Neuromuscular Blockade at Day 1 [units: participants]	**0**

No statistical analysis provided for Number of Participants With Reoccurrence of Neuromuscular Blockade at Day 1

15. Secondary: Number of Participants With Events Due to Possible Interaction of Sugammadex With Endo-/Exogenous Compounds Other Than Rocuronium [Time Frame: Day 1]

Measure Type	Secondary
Measure Title	Number of Participants With Events Due to Possible Interaction of Sugammadex With Endo-/Exogenous Compounds Other Than Rocuronium
Measure Description	Evidence of AEs due to possible interaction of sugammadex with endogenous compounds or with exogenous compounds other than rocuronium
Time Frame	Day 1
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.
AST consisting of all participants who received a dose of sugammadex

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed [units: participants]	**6**
Number of Participants With Events Due to Possible Interaction of Sugammadex With Endo-/Exogenous Compounds Other Than Rocuronium [units: participants]	**0**

No statistical analysis provided for Number of Participants With Events Due to Possible Interaction of Sugammadex With Endo-/Exogenous Compounds Other Than Rocuronium

16. Secondary: Number of Participants With Pregnancies at 30 Days Post-dose [Time Frame: Up to 30 days post -dose]

Measure Type	Secondary
Measure Title	Number of Participants With Pregnancies at 30 Days Post-dose
Measure Description	Pregnancies reported by means of a Pregnancy Reporting Form, consist of pregnant female participants or pregnant female partners of male participants
Time Frame	Up to 30 days post -dose
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.
AST consisting of all participants who received a dose of sugammadex

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed [units: participants]	**6**
Number of Participants With Pregnancies at 30 Days Post-dose [units: participants]	**0**

No statistical analysis provided for Number of Participants With Pregnancies at 30 Days Post-dose

17. Secondary: Time From Start of Administration of Sugammadex to Recovery of T4/T1 Ratio to 0.9 [Time Frame: Day 1]

Measure Type	Secondary
Measure Title	Time From Start of Administration of Sugammadex to Recovery of T4/T1 Ratio to 0.9
Measure Description	Neuromuscular function was monitored by applying repetitive train of four (TOF) electrical stimulations to the ulnar nerve every 15 seconds and assessing the magnitudes (heights) of the first twitch (T1) and fourth twitch (T4) response at the adductor pollicis muscle with a TOF-Watch® SX. Stimulation continued until the T4/T1 ratio reached at least 0.9. Higher T4/T1 ratios represent greater recovery from neuromuscular blockade; with a value of 1.0 representing full recovery.
Time Frame	Day 1
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.

Intent To Treat (ITT) group consisting of participants who received a dose of sugammadex and had at least one efficacy measurement

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed [units: participants]	**6**
Time From Start of Administration of Sugammadex to Recovery of T4/T1 Ratio to 0.9 [units: Minutes] Geometric Mean (95% Confidence Interval)	**5.11 (3.06 to 8.53)**

No statistical analysis provided for Time From Start of Administration of Sugammadex to Recovery of T4/T1 Ratio to 0.9

18. Secondary: Time From Start of Administration of Sugammadex to Recovery of T4/T1 Ratio to 0.8 [Time Frame: Day 1]

Measure Type	Secondary
Measure Title	Time From Start of Administration of Sugammadex to Recovery of T4/T1 Ratio to 0.8
Measure Description	Neuromuscular function was monitored by applying repetitive TOF electrical stimulations to the ulnar nerve every 15 seconds and assessing the magnitudes (heights) of the T1 and T4 response at the adductor pollicis muscle with a TOF-Watch® SX. Stimulation continued until the T4/T1 ratio reached at least 0.8. Higher T4/T1 ratios represent greater recovery from neuromuscular blockade; with a value of 1.0 representing full recovery.
Time Frame	Day 1
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.
ITT group consisting of participants who received a dose of sugammadex and had at least one efficacy measurement

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed [units: participants]	**6**
Time From Start of Administration of Sugammadex to Recovery of T4/T1 Ratio to 0.8 [units: Minutes] Geometric Mean (95% Confidence Interval)	**4.05 (2.36 to 6.93)**

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

19. Secondary: Time From Start of Administration of Sugammadex to Recovery of T4/T1 Ratio to 0.7 [Time Frame: Day 1]

Measure Type	Secondary
Measure Title	Time From Start of Administration of Sugammadex to Recovery of T4/T1 Ratio to 0.7
Measure Description	Neuromuscular function was monitored by applying repetitive TOF electrical stimulations to the ulnar nerve every 15 seconds and assessing the magnitudes (heights) of the T1 and T4 response at the adductor pollicis muscle with a TOF-Watch® SX. Stimulation continued until the T4/T1 ratio reached at least 0.7. Higher T4/T1 ratios represent greater recovery from neuromuscular blockade; with a value of 1.0 representing full recovery.
Time Frame	Day 1
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.
ITT group consisting of participants who received a dose of sugammadex and had at least one efficacy measurement

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Measured Values

	Sugammadex
Number of Participants Analyzed [units: participants]	**6**
Time From Start of Administration of Sugammadex to Recovery of T4/T1 Ratio to 0.7 [units: Minutes] Geometric Mean (95% Confidence Interval)	**3.41 (1.90 to 6.15)**

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

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 7 days after administration of sugammadex
Additional Description	No text entered.

Reporting Groups

	Description

Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Serious Adverse Events

	Sugammadex
Total, serious adverse events	
# participants affected / at risk	**2/6 (33.33%)**
Cardiac disorders	
Cardiac failure [1]	
# participants affected / at risk	**1/6 (16.67%)**
# events	**1**
Gastrointestinal disorders	
Intestinal ischaemia [1]	
# participants affected / at risk	**1/6 (16.67%)**
# events	**1**
Hepatobiliary disorders	
Hepatic failure [1]	
# participants affected / at risk	**1/6 (16.67%)**
# events	**1**
Respiratory, thoracic and mediastinal disorders	
Pulmonary haemorrhage [1]	
# participants affected / at risk	**1/6 (16.67%)**
# events	**1**

1 Term from vocabulary, MedDRA 12.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 7 days after administration of sugammadex
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Sugammadex	IV single bolus dose of 4.0 mg/kg sugammadex

Other Adverse Events

	Sugammadex
Total, other (not including serious) adverse events	
# participants affected / at risk	**6/6 (100.00%)**
Blood and lymphatic system disorders	
Thrombocytopenia [1]	
# participants affected / at risk	**1/6 (16.67%)**
# events	**1**
Cardiac disorders	
Arrhythmia [1]	
# participants affected / at risk	**1/6 (16.67%)**
# events	**1**
Cardiac failure [1]	
# participants affected / at risk	**1/6 (16.67%)**
# events	**1**
Gastrointestinal disorders	
Constipation [1]	
# participants affected / at risk	**1/6 (16.67%)**
# events	**1**
Hepatobiliary disorders	
Hepatic failure [1]	
# participants affected / at risk	**1/6 (16.67%)**
# events	**1**
Hyperbilirubinaemia [1]	
# participants affected / at risk	**1/6 (16.67%)**
# events	**1**
Infections and infestations	
Post procedural infection [1]	
# participants affected / at risk	**1/6 (16.67%)**
# events	**1**
Staphylococcal infection [1]	
# participants affected / at risk	**1/6 (16.67%)**
# events	**1**
Urinary tract infection [1]	
# participants affected / at risk	**1/6 (16.67%)**
# events	**1**
Metabolism and nutrition disorders	
Hypoglycaemia [1]	
# participants affected / at risk	**2/6 (33.33%)**
# events	**2**
Musculoskeletal and connective tissue disorders	
Back pain [1]	

# participants affected / at risk	**1/6 (16.67%)**
# events	**1**
Psychiatric disorders	
Restlessness [1]	
# participants affected / at risk	**1/6 (16.67%)**
# events	**1**
Renal and urinary disorders	
Haematuria [1]	
# participants affected / at risk	**1/6 (16.67%)**
# events	**1**
Skin and subcutaneous tissue disorders	
Decubitis ulcer [1]	
# participants affected / at risk	**1/6 (16.67%)**
# events	**1**
Subcutaneous emphysema [1]	
# participants affected / at risk	**1/6 (16.67%)**
# events	**1**

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: In case a proposed publication contains reference to an invention owned by the sponsor or to which the sponsor otherwise has rights, the sponsor may request a reasonable suspension of the publication.

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:

Cammu G, Van Vlem B, van den Heuvel M, Stet L, el Galta R, Eloot S, Demeyer I. Dialysability of sugammadex and its complex with rocuronium in intensive care patients with severe renal impairment. Br J Anaesth. 2012 Sep;109(3):382-90. doi: 10.1093/bja/aes207. Epub 2012 Jun 24.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00656799 History of Changes
Other Study ID Numbers:	P05773 2007-006934-33 (EudraCT Number)
Study First Received:	April 7, 2008
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Health Authority:	Belgium: Federal Agency for Medicinal Products and Health Products

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