



Informed Consent Form

Official Title : Comparison of Operating Conditions, Postoperative Recovery and Overall Satisfaction
Between Deep and Restricted Neuromuscular Blockade for Spinal Surgery Under
General Anesthesia

Identifiers : NCT02724111

Date of Document : 9th June 2016



[KUMC II. 01-04] Standard Informed Consent Form (for Adult)

Guideline for Research Subjects' Consent

Research Title	Effect of Neuromuscular Blockade on Operating Conditions and Overall Satisfaction During Spinal Surgery
Principal Investigator	<i>Byung Gun Lim</i>

The purpose of this guideline is to help you gain understanding of this research, and it contains details about the research. Please read carefully before deciding whether or not you will participate in this research.

A goal of a research is to explore and investigate undiscovered areas. It is important that you are given sufficient information regarding the research and understand such information as the objective, process, subject candidates, potential risk/benefit, discomfort, etc. before you decide to participate.

You can talk this over with your family or others before you decide. If you decide to take part in the research, please fill out and sign the consent form.

If you decide to participate in the research, you will be asked to voluntarily fill out the informed consent form before participation. You may decide not to participate. Even if you decided not to, you will not experience any losses nor disadvantages in your treatment.

1. Background and Objective of Human Research

Neuromuscular blockade (NMB; muscle relaxation) during abdominal or laparoscopic surgery under general anesthesia is known to be effective for facilitating the surgical procedure by improving the surgical condition. However, there was no report about the effectiveness in spine surgeries yet. Therefore, we aim to investigate operating conditions, postoperative recovery and overall satisfaction of surgeons between the different degrees of NMB (deep NMB group and restricted [shallow] NMB) for spine surgery under general anesthesia.

2. Number of Subjects and Research Venue

This research will be conducted with 90 subjects in Korea University Guro Hospital.

We plan to recruit 90 subjects in our hospital, and the research will be conducted for 12 months.

If you decide to proceed with the trial, please be noted that the trial will last 12 months, during this period, you are slated to visit total of 2 times, and each visit will take 1 hour in average.

3. Method and Process of Clinical Research

The research process for participants is as follows.

If you decide to participate with this research, you will be asked to fill out the "Informed Consent Form". If you have any questions regarding the research, you may talk to any research staff. After you sign the consent form, the investigator will take your medical



history to check if you meet the criteria for registration.

(Randomization)

When you are determined to be appropriate by the screening process, you will be randomly assigned to either one of two groups. 1:1 randomized assignment (which has equivalent possibility of coin flipping) will be used for assignment to either group treated with deep NMB (Group DB) or group treated with restricted (shallow) NMB (Group RB).

The methodology of the research is: [questionnaires, application of anesthetic method including muscle relaxant, grading scale, etc.] In the questionnaire, you will be asked of expected outcome, satisfaction, etc. in both groups. Filling out the questionnaire will take about 60~90 minutes.

For both groups, you are just required to answer several questions in the recovery room and to record any adverse event during the postoperative 24 hours. During the anesthesia and surgery, the investigator will observe and record the required data.

Some tests or procedures in the research are provided regardless of participation of the research, as they are included in standard treatment process. Tests or procedures additionally provided by the research are as follow.

- 1) A train-of-four (TOF, frequency 2 Hz, current 50 mA, interval 15 sec) monitoring using an accelerator device (TOF-Watch SX; Organon Ltd, Ireland) for assessment of NMB degree.
- 2) Pressure monitoring of the back muscle retractor using the probe and device for intracranial pressure measurement

4. Expected Benefit of Participating in Human Research

Sugammadex, the powerful reversal agent of NMB will be given to the participants for free during the surgery.

Additional inspection about sedation, satisfaction, and adverse events including nausea or vomiting, pain will be checked by the investigator during the postoperative period of the clinical trial.

In addition, it is a great help to improve the surgical condition in patients undergoing spine surgery under general anesthesia and similar groups alike.

5. Possible Risks, Side Effects and Discomfort from participating in the research

Over the course of your participation, inconvenience might occur as you are expected to make 2 visits to the hospital for screening and interviews. No additional discomfort, inconvenience, risk associated with additional monitoring devices is expected. The participation in the research does not affect your standard treatment process including anesthetics, muscle relaxant, reversal agents such as sugammadex, pyridostigmine or analgesics, and therefore standard treatment will be provided even if you decide not to participate.

6. Expenditure in Research Participation

Much of the tests or procedures you will be receiving are included in standard treatment processes regardless of your participation, and therefore the additional cost of such tests or procedures will not be charged to you. Rather, sugammadex, the powerful and expensive reversal agent of NMB will be given to the participants for free.

Still, other tests or procedures including TOF or retractor pressure monitoring for research purpose that are not included in standard treatment processes, will not be charged to you, as they will be paid for by the investigator (or the sponsor MSD pharmaceutical company). Please note that the research is funded by MSD pharmaceutical company.



7. Compensation for Research Participation

No compensation will be provided when you participate in clinical research

8. Compensation and/or Treatments in Case of Damage or harm

The process of the research does not deviate from the standard treatment process which you will experience even if you decide not to participate. Therefore, usual safety protection measures will be applied to your treatment process, and information about the research objective and methods will be adequately provided prior to the initiation of the research. If, over the course of your participation, any expected or unexpected adverse events occur due to procedures or interventions outside the standard treatment process, you will be provided with the best treatment possible.

9. Participant's Obligation

Over the course of your participation, you are expected to follow below instructions:

As you participate in the research, you are expected to follow schedules provided by the investigator, and make total of 2 hospital visits. Over the course of the research, please notify the investigator if you experience any discomfort. If you have any questions regarding above matters, please contact the investigator and you will be provided with necessary information.

10. Withdrawal from Clinical Research

Participants will be withdrawn by the investigator for the reasons described below.

- a. Whenever participant wants to be withdrawn from the research.
- b. When participant cannot follow the schedules and protocols of the research.

Participants will continue to be provided with the proper NMB treatment during the surgery even after they drop out of the research; the investigator will perform postoperative visit and follow-up to protect participants' safety.

Participants' personal information collected before dropping out will be used for the research, but no additional personal information will be collected thereafter.

11. Privacy Policy for Collecting, Using Personal (sensitive) Information and Providing it to The Third-party

The investigator requires additional consent from participants in case of collecting sensitive data such as health and gene information, and in case of providing data to the third-Party.

*** This applies when the information is used for secondary purpose, outside the pertaining research.**

By signing this consent form, your personal (sensitive) information will be collected and used by the investigator, and can be provided to third-party.

*** For more information, please read below.**

1) Purpose of collecting and using personal information

Report of significant adverse events



2) List of personal (sensitive) information

Participant's name, gender, age and hospital registration number

Health-related information such as medical records and documents in the process of clinical research

3) Period of retaining and using personal information

Your personal (sensitive) information is to be stored and used while participating in clinical research. After the termination of the research, the personal information will then either immediately be terminated or kept as a record for five additional years from the date of the termination.

4) Right to refuse and disadvantages due to refusal

Participants have the right to decide freely in clinical research whether they provide personal (sensitive) information or not during any phase of the clinical research process. If participants do not allow to be provided their personal information, he or she will not experience any losses or disadvantages.

5) Provision of Personal Information to Third-Party

Collected personal (sensitive) information from following research will not be allowed to use for other purposes except the report of significant adverse events. In case of providing participants' personal information, the identifiable personal information will be not included. If participants wish to give his or her consent to providing their personal information, please fill out the "Consent Agreement Form."

12. Privacy Policy of Personal Information and Record

Collected personal information while participating in clinical research will be protected with complete confidentiality and if the research results are reported, published or announced, participant's identity will not be revealed.

Monitor/Auditor, IRB(Institutional Review Board), Relevant Government Agencies (ex: Ministry of Food and Drug Safety, Ministry of Health and Welfare Affairs, and etc.) are able to access your medical records to inspect the procedures and reliability, to the extent that does not violate your privacy, as per relevant policy.

13. Right to Participate or Withdraw

You have a right to withdraw from the research at any time. In this case, participation will be terminated by the investigator, and the investigator will not collect additional information afterwards. If you do not want the investigator to use collected information in clinical research, please inform the investigator.

Your decision will not influence treatment you receive. If you decide not to participate or withdraw from the research, you will not experience any losses nor disadvantages. If you do not want to participate, please inform the investigator.

If the investigator collects new information, which influence the determining of participating in clinical research, the investigator should provide it at the right time to participants or representatives.

If the investigator collects new information which is deemed significant in your decision making, the investigator will inform you or your representative of the information at appropriate time.

14. Contact Information

All the question about the clinical research will and can be answered by the investigator or staffs. Please feel free to contact us by phone, e-mail, or fax if you or your representatives have any questions during anytime you desire.



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If you'd like to know more about your rights, contact the research staff or below numbers. The research was reviewed and approved by Korea University Guro Hospital Institutional Review Board.

Office of IRB: 02-2626-1632, 1639, 1659

Office of Quality Assurance: 02-2626-1863



Participant's Consent Form

Research Title: Effect of Neuromuscular Blockade on Operating Conditions and Overall Satisfaction During Spinal Surgery

► please check "V" in the box if you consent to below items.

(Check)	I have read this statement and fully understand the objective, method, expected outcomes, possible risks, other treatment options, and management of health information, of this research
(Check)	All my questions were answered.
(Check)	I understand that I can withdraw from this research anytime I desire even after my consent, and that I will receive appropriate treatment after my withdrawal.
(Check)	I understand collection/using/offering of personal information for the purpose of research
<ul style="list-style-type: none"> • Do you agree to allow your personal information to be used for purpose of other researches? <p><input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No (If "yes", please check the question as described below)</p> <ul style="list-style-type: none"> • Do you agree to offer your personal identifiable information? <p><input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No</p>	
(Check)	I have received a copy of the guideline and written and filled out consent form.
(Check)	You agree to participate in this clinical research voluntarily with full consideration. I consent to participate in this research on my own free will, after full consideration with sufficient time.

► Check items that apply to your consent

Person received statement	Relationship	Name	Signature	Date of Issue (yyyy/mm/dd)
	<input type="checkbox"/> Participant himself or herself			
	<input type="checkbox"/> Representative			
	<input type="checkbox"/> Spouse, <input type="checkbox"/> Father, <input type="checkbox"/> Mother, <input type="checkbox"/> Brother or Sister (), <input type="checkbox"/> Other ()			
	<input type="checkbox"/> Witness(if necessary)			
Provider of statement	Relationship	Name	Signature	Date of Issue (yyyy/mm/dd)
	<input type="checkbox"/> Principal Investigator			
	<input type="checkbox"/> Delegated Sub-Investigator			

※ This Consent Form can be signed by Principal Investigator or IRB-approved Sub-Investigator only.

※ This IRB-approved consent form is valid ONLY with KUMC's seal