

HOSPITAL FOR SPECIAL SURGERY

535 East 70th Street
New York, NY 10021

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

TITLE: The effect of dexmedetomidine dose on motor evoked potentials during spine surgery: A randomized, single-blind trial.

PROTOCOL NO.:

SPONSOR:

INVESTIGATOR: Ronald Emerson, M.D.

SITE(S): HSS operating room, Belaire, 5th floor

STUDY-RELATED PHONE NUMBER(S): 774-2942

IRB #:2017-1304

You are being asked to take part in a research study conducted by Hospital for Special Surgery (HSS). You are being asked to participate in this study because you are having surgery to correct curvature of the spine.

You will still be responsible for the cost of your medical care just as you would be if you were not part of this study. For example, any co-pays, deductibles, and co-insurance associated with your medical care.

This document provides you with information about this study. After reading this document, any questions you may have will be answered. You may take home a copy of this document to consider or discuss with family and friends before making your decision.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

1. WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine the effect of dexmedetomidine, an anesthetic, on testing that we do during spine surgery to monitor the spinal cord. The testing is called motor evoked potential monitoring, and it monitors the parts of the spinal cord that are important to movement of the arms and legs. All anesthetics interfere to some degree with this monitoring. We are attempting to develop the best anesthetic mixture to provide safe and effective general anesthesia

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while maximizing our ability to monitor the spinal cord. The addition of intravenous dexmedetomidine to the general anesthetic may help us to improve safety, by reducing the use of other agents and making it possible to wake up faster once the surgery is over. Dexmedetomidine is not new. It was approved by the FDA in 1999, and is used routinely at HSS. Your participation in this study will take place during your operation.

During spinal surgery, it is normal for your anesthesiologist to replace fluids that are lost from your circulation during the surgery. We will use a device called the NICOM monitor to measure the output of your heart, which is related to the amount of fluid in your circulation. The NICOM monitor does this using four small pads that stick to your chest. We will analyze your motor evoked potential monitoring to see if the small changes that we often see during spinal surgery are related to the amount of fluid in your circulation. We will do this to see if motor evoked potential monitoring is helpful for guiding replacement of fluids.

2. WHAT WILL YOUR PARTICIPATION REQUIRE?

If you decide to be in this study, the following research procedures will be performed: you will receive one of two different anesthetic treatments during surgery, both of which are standard of care. Regardless of the treatment used, you will not feel any pain during surgery. One treatment will include intravenous propofol and a lower dose of dexmedetomidine. The other will include lower dose of intravenous propofol and a higher dose of dexmedetomidine. The treatment to be administered will be determined randomly – rather like the flip of a coin. Only the anesthesiologist will know the anesthetic treatment being used; other members of operating room team, including the surgeon, will not know.

If you decide to be in this study, we will also use a NICOM monitor.

It is not known which anesthetic treatment is superior and will be most benefit to you. It is hoped the knowledge gained will benefit others in the future.

You and/or your insurance will be responsible for any costs of all procedures performed that are standard of care, that is, care that you would receive even if you were not in this study.

A total of 68 subjects will participate in this study at HSS.

Your participation will be limited to your surgery. There will be no extra visits.

3. WHAT ADVERSE (BAD) EFFECTS CAN HAPPEN FROM BEING IN THE STUDY? WHAT RISKS ARE KNOWN ABOUT THE STUDY DRUG/STUDY DEVICE?

The known effects, discomforts and foreseeable risks of physical, psychological, sociological, or other harm which you may reasonably expect to occur from being in this study is the risk of awareness, i.e. not being fully asleep, during surgery. If this happens, it will not be possible for you to report this during surgery. However, the risk of awareness should be no greater during

this study than during other operations for curvature of the spine, which is routinely performed using mostly or total intravenous anesthesia.

In order to reduce the likelihood of awareness, you will also receive intravenous diazepam (Valium) during surgery.

Motor evoked potential monitoring entails a small risk of tongue bite, but that risk is not altered by participation in this study since the will be used as a necessary part of your surgery.

The use of the NICOM monitor uses four small stick-on chest pads, and does not add any risks.

Participation in this research involves the potential risk of a breach of confidentiality to your stored health information. HSS tries to minimize those risks by (i) removing some direct identifiers from stored information [(i.e., names, social security numbers, medical record numbers; (ii) securing, in a separate location, and limiting access to information that would identify you; and (iii) limiting access to information stored to HSS investigators.

There may be risks or side effects that are unknown at this time.

Your condition may not get better from being in this study.

4. WHAT BENEFIT CAN YOU EXPECT?

This study is comparing two standard of care anesthetic treatments to determine which may be more effective. The knowledge gained from this study may benefit others in the future. There is no direct benefit from participating in this research.

5. COST

There will be no cost to you for participation in this study because this study does not involve any additional visits, tests, or procedures.

You will still be responsible for the cost of your medical care, and for any co-pays, deductibles, and co-insurance associated with your medical care, just as you would be if you were not part of this study.

HSS is committed to providing financial assistance when financially warranted and consistent with its resources, regardless of age, gender, religion, race or sexual orientation. So if you do not have health insurance, or if your health insurance does not pay for your medical care, you may seek financial assistance from HSS. Eligibility determinations are made on a case-by-case basis in accordance with HSS's financial assistance policy. You will be responsible for any costs not covered by financial assistance, which could be all of the costs (if HSS determines that you are not eligible for financial assistance) or some of the costs (if financial assistance awarded by HSS

does not cover all of the costs). For more information about the Financial Assistance Program or to request a [Financial Assistance Application](#) call (212) 606-1505 to speak with a Financial Assistance Counselor or you can visit the following site: <http://www.hss.edu/patient-financial-assistance-notice.asp>.

6. PREGNANCY

Due to inherent risks, HSS policy prevents women who are pregnant or nursing a child from receiving the type of surgery needed to qualify for this research study. So, if you are currently pregnant or nursing a child, you may not participate in this study.

7. PAYMENT FOR PARTICIPATION

You WILL NOT be paid for your participation in this study.

8. COMMERCIAL ISSUES: YOUR RIGHTS IN THE RESULTS OF THE STUDY

There are no plans to compensate you for the use of the findings of this study, or any of the information or biologic materials (such as blood or tissue) collected from you during the study, even if they are used to develop or make a commercial product (such as a drug, device, biologic substance, or test).

9. ALTERNATIVES: WHAT OTHER TREATMENT IS AVAILABLE IF YOU DON'T WANT TO BE IN THE STUDY?

You do not have to participate in this study to receive treatment for your condition.

If you decide not to be part of this study, you will still receive MEP monitoring during surgery. You will receive anesthesia as decided by your attending anesthesiologist, which could include one of the two treatments that is being used in this study.

You should ask the study doctor about other alternative treatments that may be available for your condition.

10. WHO WILL BE ABLE TO SEE YOUR RECORDS AND PERSONAL INFORMATION AND KNOW THAT YOU ARE IN THE STUDY?

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to see your information and why they will be able to see it. The study doctor must obtain your authorization (permission) to use or give out any health information that might identify you.

What information may be used or given to others?

If you choose to be in the study, the study doctor will get personal information about you. The information might identify you. The study doctor may also get information about your health including:

- Medical and research records
- Records about surgery
- Records of physical exams
- Records about phone calls
- Laboratory, x-ray, and other test results

Who may use, disclose, or receive my information?

The following person(s) class(es) of persons, and/or organization(s) may use, disclose, or receive my information:

- The Principal Investigator and other Investigators for this study, including your study doctor.
- The research coordinator, research nurses, and other members of the HSS research team working on this study.
- Every research site for this study, including Hospital for Special Surgery and its affiliates, New York-Presbyterian Hospital, and Memorial Sloan-Kettering Cancer Center. This includes the research staff and medical staff at each institution.
- The Patient Advocate or Research Ombudsman at these institutions.
- Staff members of HSS responsible for administering clinical trials and other research activities
- Any laboratories and other individuals and organizations that analyze your health information for this study.
- Any health care provider that you have used in the past or may use up to the time this study ends.
- The sponsor of this study. “Sponsor” includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor.
- Any Contract Research Organization (CRO) the sponsor may use. (A CRO is an independent entity with which a research sponsor contracts to oversee and facilitate various aspects of the clinical research process on the research sponsor’s behalf.)
- The United States Food and Drug Administration (FDA), the federal Office for Human Research Protections (OHRP), any federal agency that provides support for this study, and any federal, state, or local agency responsible for overseeing HSS, the study doctor, or any other member of the HSS research team involved in this study.
- The members and staff of the affiliated Institutional Review Boards (IRBs) at HSS, New York-Presbyterian Hospital, and Memorial Sloan-Kettering Cancer Center. An IRB is a committee of health care providers, community representatives, and others that initially

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approves and periodically reviews biomedical and behavioral research that involves human subjects in order to protect the rights, safety and welfare of study participants.

- Data Safety Monitoring Boards and others authorized to monitor the conduct of this study for safety or quality assurance, for example a Clinical Events Committee.

Why will this information be used and/or given to others?

Your health information may be given to others to carry out this study. The sponsor will analyze and evaluate the results of this study. People working for the sponsor also visit HSS and other research sites to make sure this study is being done correctly.

Your health information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can get approval to market new products resulting from this study. Your information may also be used to meet the reporting requirements of governmental agencies.

The results of this study may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

What if I decide not to give permission to use and give out my health information?

By signing this informed consent form, you are giving permission to use and give out your health information as described above. If you refuse to give permission, you cannot be in this study.

May I review or copy the information obtained from me or created about me?

You have the right, in accordance with Hospital policy and applicable law, to review and copy your health information that is created or obtained in the course of this study. However, if you decide to be in this study and sign this informed consent form, you will not be able to look at or copy your information until after the study is completed if doing so would impact the validity of the study (for example, if the study is “blinded” so that during the study you will not know what treatment or other intervention you are receiving).

May I revoke (take back) my permission?

Yes. Your permission will never expire unless you revoke it. To revoke your permission, you must write to the study doctor at Hospital for Special Surgery, 535 East 70th Street, New York, NY 10021.

You may revoke your permission to use and disclose your health information at any time. If you revoke your permission, you cannot continue to participate in this study.

After you revoke your permission, no new health information that might identify you will be gathered. Information that has already been gathered may still be used and given to others. This would be done if the information is needed for this study to be reliable.

Is my health information protected after it has been given to others?

Some persons who receive your health information may not be required to protect it, and they may share your information with others without your permission, if permitted by laws governing them. Therefore, there is a risk that your information will be released to others without your permission.

11. CONFLICT OF INTEREST NOTIFICATION

HSS is concerned about possible conflicts of interest in research, and has policies that require all investigators and senior research staff to report to HSS significant financial interests (such as stock ownership, royalty payments, and consulting agreements) and relationships (such as membership on a scientific advisory board) that are related to their research studies. When an investigator reports a significant financial interest or relationship that relates to one of his/her studies, HSS's Conflict of Interest Committee for Research reviews the information to evaluate the risk that the interest or relationship might influence how the investigator conducts the study or interprets the results of the study. HSS may also take steps to minimize that risk.

- The Conflict of Interest Committee for Research has determined that there are no conflicts of interest associated with this study.

12. VOLUNTARY PARTICIPATION/WITHDRAWAL

Your decision to take part in this study is completely voluntary. You are free to choose not to take part in the study and may change your mind and withdraw at any time. Your relationship with physicians at HSS and your medical care at HSS, now or in the future, will not be affected in any way if you withdraw or refuse to participate. You will not lose any benefits to which you are otherwise entitled.

The study doctor and/or the sponsor may terminate your participation in this study at any time without your consent if, in their judgment, it is inadvisable for you to continue.

13. COMPENSATION FOR INJURY

If you are injured as a result of participating in this study, the study doctor, other members of the research team, or other HSS professional medical staff will provide you with emergency medical treatment (or arrange to have such treatment provided to you), and will assist you in obtaining appropriate follow-up medical treatment. However, there is no plan to routinely provide compensation for additional medical care or other costs.

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Your health insurance may or may not pay for treatment of injuries as a result of your participation in this study.

14. SOURCE OF FUNDING

Funding for this study will be provided by the HSS Department of Neurology.

15. QUESTIONS

If you have any additional questions later on, or if you wish to report a medical problem that may be related to this study, Dr. Emerson can be reached at 212-774-2742 during office hours and at 212-606-1050 after business hours.

If you have any questions about your rights as a participant in this study or any questions about your participation that you would like to ask an institutional representative who is not part of this study, you can call the Manager of the HSS Institutional Review Board at (212) 774-7154.

If you would like to have more information about the Hospital's financial disclosure review process in general, or in regard to this study, you may contact the Hospital's Office of Legal Affairs at (212) 606-1592. You may also ask the Hospital's patient advocate at (212) 774-2403, to arrange for you to have this information.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Agreement to Participate: Witnessing and Signature

To be in this study, you or your legal representative must sign the next page of this informed consent form. By signing the next page, you are voluntarily agreeing to be in this study at HSS.

Before signing, you should be sure of the following:

- You have read all of the information in this “Informed Consent to Participate in Research” form (or had it read to you).
- You have discussed the implications of your being in this study with your doctor, your study doctor and/or the study coordinator.
- You have had the chance to ask questions about this study.
- You received answers to your questions.
- If you did not understand any of the answers, you asked the study doctor or the study coordinator to explain them to you.
- The information given to you is based on what is now known about the study drug(s), device(s), or procedure(s). There may be other risks or complications that are not known at this time.
- You have had time to think about the information and decide whether or not to be in the study.

Please check one of the following:

- I AM NOT in another research study at this time.
- I AM in another research study at this time.

If you decide to be in this study:

- You are expected to follow the study procedures.
- You are expected to provide the information needed by the study doctor, the study coordinator, nurses, or other staff members for the study.
- You will be told in a timely manner of any significant new information that may affect your willingness to stay in the study.
- You may freely choose to stop being in the study at any time.

By signing below, you are voluntarily agreeing to be in this study.

You must be given a signed copy of this informed consent form to keep for yourself.

_____	_____	_____
Print Name of Participant	Signature of Participant	Date
_____	_____	_____
Print Name of Parent/Legal Guardian (if applicable) ¹	Signature of Parent/Legal Guardian	Date
_____	_____	_____
Print Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

As an HSS representative, please sign here to indicate that you have given a signed copy of this informed consent form to the participant

NOTE TO INVESTIGATORS:

- **THE ORIGINAL OF THIS INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S STUDY FILE.**
- **A SIGNED COPY OF THIS INFORMED CONSENT FORM MUST BE GIVEN TO THE PARTICIPANT.**
- **A COPY OF THE INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S HOSPITAL MEDICAL RECORD IF THE PARTICIPANT IS (OR WILL BE) HOSPITALIZED AT ANY TIME DURING THE STUDY.**

¹ The parent or legal guardian of a child participant should sign this form on behalf of the child. The signature of one parent is sufficient when the research is of minimal risk to the child, or when the research presents the prospect of direct benefit to the child. The signature of both parents is required when the research involves greater than minimal risk with no prospect of direct benefit to the child. The requirements for signature of both parents may be waived if one parent is deceased, unknown, incompetent, or not reasonably available, or when one parent has sole legal responsibility for the care and custody of the child. If the participant is a child who is capable of giving assent, the child should also sign the attached Assent Form.

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