



Electroencephalogram Studies of Induction and Recovery from Propofol Induced General Anesthesia

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Who are we?

This research is being conducted by the Massachusetts General Hospital Department of Anesthesia and Critical Care. Our research team consists of anesthesiologists, neuroscientists, and biomedical engineers who are interested in learning more about how anesthetics work in the brain.

What is this study about?

The purpose of this study is to investigate how the commonly used general anesthetic drug propofol works in the brain to produce loss of consciousness. Propofol is an intravenous medicine used daily in the United States and around the world to put patients to sleep under general anesthesia. Propofol produces drowsiness in low doses and general anesthesia (drug-induced “sleep”) at higher doses. During this experiment, you will receive propofol at a sufficient dose to induce general anesthesia. While under anesthesia, your brain waves will be measured using electroencephalogram (EEG). On a separate day, your brain will be imaged using magnetic resonance imaging (MRI).

Who qualifies for this study?

You must be a healthy, non-smoking person between the ages of 18 and 36 years. You also must be able to lie flat without difficulty.

Who does NOT qualify for this study?

For safety reasons, you do not qualify for this study if you have:

- A drug allergy to any of the medicines we will use
- Moderately severe heart disease
- Moderately severe lung disease
- Blood disorders
- You must not be pregnant or breast-feeding
- History of neurological disorders
- Previous serious head injury or brain surgery
- Claustrophobia
- Metal implants such as pacemakers, neurostimulators, or heart valves
- Metal injury to eyes

What will take place during this study?

Once you contact the study staff, you will be provided general information about the study, and any questions you have about the study will be answered. After you tell the study staff that you are interested in the study, there will be a short question and answer session over the phone to determine your eligibility. If the question and answer

session shows that you might be eligible, you will visit the hospital for a medical examination by an anesthesiologist. This examination will determine whether or not you can safely participate in this study. During this visit, the anesthesiologist will review your medical history, perform a physical examination, and take a urine sample. The anesthesiologist will also perform an electrocardiogram (ECG) and a hearing test. A study nurse will be taking a small sample of blood to ensure that it is safe for you to participate in the study. If this medical examination shows that you can safely participate, you will then be invited to enroll in the study. This medical examination will last 1-2 hours.

On the day of the study, you must have nothing to eat or drink for 8 hours before the start of the study. The study will take place at the Mass General Hospital General Clinical Research Center in the Charlestown Navy Yard. When you arrive, you will change into a hospital gown. You will then have high resolution anatomic MRI scans taken of your brain. It is important to remain motionless throughout the MRI scanning procedure. Before starting the MRI scans, the study staff will work with you to adjust your head and body position so that you will be comfortable lying motionless throughout the MRI scan. Preparation for the anesthesia study will begin by placing EEG electrodes on your scalp and connecting you to standard anesthesia monitors. Anesthesia will then be administered. After the study, you will be allowed to wake up from anesthesia in the usual way in a recovery area. Once you have fully recovered, which usually takes 1-2 hours, you will be discharged.

You must have a responsible adult available to escort you home when you have completed the study. This responsible adult escort must be present regardless of the mode of transportation you choose (for example, even if you take a cab or the bus). You cannot drive a motor vehicle, operate heavy machinery, drink alcohol, take any narcotic medicines or any medications that can cause drowsiness, or participate in any activity that requires alertness until 24 hours after the study is finished.

How many visits will be required to complete the study?

Two visits will be required to complete the study: One for the medical evaluation and one for the MRI scan and EEG recordings under General Anesthesia.

Will there be any costs to me or my insurance company to participate?

No charges will be billed to you or your insurance company for this study.

Will I be reimbursed for parking or transportation costs?

Yes, you will be reimbursed up to \$20 for transportation and parking costs.

Will I be compensated for participating in this study?

Yes, you will receive \$200 for successful completion of this study. If you are unable to complete the full study, you will receive a pro-rated amount based on the amount of the study completed.

What are some important points to remember if I participate in this study?

- For safety reasons, on the day of the study, you must have nothing to eat or drink for 8 hours before the study begins.
- You must have a responsible adult available to escort you home when you have completed the study. This responsible adult escort must be present regardless of the mode of transportation you choose (for example, even if you take a cab or the bus). You cannot drive a motor vehicle, operate heavy machinery, drink alcohol, take any narcotic medicines or any medications that can cause drowsiness, or participate in any activity that requires alertness until 24 hours after the study is finished.
- It is important to remain motionless throughout the MRI scanning procedure. Before starting the MRI scans, the study staff will work with you to adjust your head and body position so that you will be comfortable lying motionless throughout the MRI scan.

Who do I contact for more information?

For more information, please contact Dr. Emery Brown or Dr. Eric Pierce in the MGH Department of Anesthesia and Critical Care at (617) 724-9857.