INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

The effect of precurarization with Rocuronium on the incidence and severity of Succinylcholine-induced fasciculations and myalgias in a high volume ERCP center.

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

TAKING PART IN THIS STUDY IS VOLUNTARY

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled, and will not affect your relationship with Indiana University Hospital.

WHY IS THIS STUDY BEING DONE?

Succinylcholine is a medication (muscle relaxant) that is used as part of the anesthetic (going to sleep) for surgery. This medication often causes muscle soreness. Rocuronium is a medication (muscle relaxant) that some researchers believe may reduce muscle soreness caused by succinylcholine, but this has not been proven. Some anesthesiologists pretreat patients with rocuronium before giving patients succinylcholine, and some do not. The purpose of this study is to figure out if pretreatment (treating or medicating someone before symptoms appear) with rocuronium reduces the side effects (muscle soreness) of succinylcholine.

You were selected as a possible participant because you are having an endoscopic retrograde pancreatography (ERCP) done at University Hospital. You do not use opioids over a specified amount daily and you are not high risk for aspiration (when your stomach contents come up into your mouth and go into your lungs).

The study is being conducted by Leighan Bye MD, PhD, Yar Year, MD, Jennifer Stewart, MD, Elizabeth Kroepfl, MD, and Zonair Khan, medical student IU school of Medicine, Department of Anesthesiology. This study is not funded.

HOW MANY PEOPLE WILL TAKE PART?

If you agree to participate, you will be one of 300 participants taking part in this research.

WHAT WILL HAPPEN DURING THE STUDY?
If you agree to be in the study, you will do the following things:

You will be randomized (by chance, like flipping a coin) into one of 3 arms. You may receive the pretreatment medication rocuronium prior to receiving the succinylcholine or you may not. Arm 1 will not receive rocuronium pretreatment. Arm 2 will receive rocuronium pretreatment followed by succinylcholine 1 minute after pretreatment. Arm 3 will receive rocuronium pretreatment followed by succinylcholine 2 minutes after pretreatment. You will get an anesthetic for your ERCP just like you would if you didn't participate. Your ERCP will take place as usual. 3 hours after the succinylcholine was given to you, you will be asked a few questions about how you feel. 24 hours after the succinylcholine was given to you, you will be asked the same questions about how you feel, possibly by phone call if you have already gone home.

The study team will collect information about you from your medical records and use it for this study.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?
While participating in the study, the risks, side effects, and/or discomforts include:

Roughly half of the practicing anesthesiologists at the University Hospital pretreat with rocuronium and the other half don't pretreat with rocuronium. Rocuronium may cause minor burning at the injection site and, as with any drug, there is risk for allergic reaction (e.g. anaphalaxis). We are attempting to standardize anesthesia practice and see which way is better. There are no added risks for receiving the drugs rocuronium and succinylcholine, or succinylcholine alone, as a part of this study. Without being in this study, there is a chance that your anesthesiologist may pretreat you with rocuronium or treat you with succinylcholine alone anyways.

You will be asked to complete a verbal survey 2 times, the day of the procedure and the day following, which you may find tiresome.

There is always a risk of loss of confidentiality.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?
We don't expect you to receive any benefit from taking part in this study, but we hope to learn things which will help anesthesiologists in the future.

HOW WILL MY INFORMATION BE PROTECTED?
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, and any state or federal agencies who may need to access your medical and/or research records (as allowed by law). State and federal agencies may include the Food and Drug Administration (FDA).

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

WILL I BE PAID FOR PARTICIPATION?

You will not be paid for participating in this study.

WILL IT COST ME ANYTHING TO PARTICIPATE?

You or your insurance company will be responsible for the procedure that you are randomized into during your hospital stay, as those are all routine standard of care procedures. You or your insurance company will be responsible for all of the study drugs that will be administered since all of the study drugs are being given as part of standard of care. There may be a difference in the cost of the study drugs, depending on which arm you are randomized into. You or your insurance will also be billed in the usual manner for the costs related to any routine medical care and treatment.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?

In the event of physical injury resulting from your participation in this study, necessary medical treatment will be provided to you and billed as part of your medical expenses. Costs not covered by your health care insurer will be your responsibility. Also, it is your responsibility to determine the extent of your health care coverage. There is no program in place for other monetary compensation for such injuries. However, you are not giving up any legal rights or benefits to which you are otherwise entitled.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study (or research related injury) contact the researcher Leighan S. Bye at 317-274-0275. After business hours, please call 317-944-5000.

In the event of an emergency, you may call the 24hour hospital line at 317-944-5000.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

CAN I WITHDRAW FROM THE STUDY?

If you decide to participate in this study, you can change your mind and decide to leave the study at any time. If you decide to withdraw, you will simply explain to the person asking about your post procedure pain that you no longer wish to participate. There is no risk to you for withdrawing and your data / medical records will not be included in the final analysis.

PARTICIPANT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Participant's Printed Name:_____

Participant's Signature:_____ **Date**:_____

Printed Name of Person Obtaining Consent:_____

Signature of Person Obtaining Consent:_____ **Date**:_____