Title: Comparison of Etomidate Plus Propofol, Etomidate Alone on Induction of Anesthesia

NCT03820388

Document Date: September 26, 2017

Title of research study: Comparison of Etomidate and Propofol Vs Propofol, Etomidate Alone on Induction of Anesthesia: A Pilot Observational Study.

Investigator: Hong Liu, MD

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are scheduled for an elective surgery at the UC Davis Pavilion Operating Room.

What should I know about a research study?

(Experimental Subject's Bill of Rights)

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any drug or device to be used.
  - Any common or important discomforts and risks.
  - Any benefits you might expect.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team. During business hours, contact:

Ana Arias, Department of Anesthesiology & Pain Medicine, Office: 916 703-5456

Outside normal business hours, contact:

Hong Liu, MD office: 916 734-2949 or pager (24 hrs) 916 816-9144

To contact Dr. Hong Liu on his pager, dial his pager phone number. After the tone, enter the phone number where you can be called, press the # key and hang up. He will call you back on the phone number that you provided.

For non-emergency issues you can call the UCDMC Hospital Operator (916-734-2011), tell the Operator you are participating in a research study and you wish to talk to the Anesthesia Resident on-call. In the case of an emergency, dial 911 from any phone.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). Information to help you understand research is on-line at http://www.research.ucdavis.edu/policiescompliance/irb-admin/.You may talk to a IRB staff

member at (916) 703-9151, hs-irbadmin@ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Why is this research being done?

This is a research study conducted by Hong Liu, MD from the Department of Anesthesiology and Pain Medicine. We will be collecting data to help us determine the safety of medications used when you are being put under for surgery. The medication includes etomidate plus propofol, propofol alone, or etomidate alone. Both etomidate and propofol are FDA-approved medications and are commonly used during the induction of anesthesia

How long will the research last?

We expect you will be in this research study once you have given your consent to participate, while you undergo surgery for your procedure, during your recovery from surgery in the hospital and up to 24 hours after you received the induction medication.

How many people will be studied?

We expect 75 people participants enrolled here at UC Davis Medical Center.

What happens if I say yes, I want to be in this research?

Once you have signed your consent to participate, as well as the HIPAA authorization form, you will be placed randomly into one of three groups: Group 1 receives propofol, Group 2 receives etomidate, and Group 3 receives etomidate plus propofol as their induction agent.

The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have a one in three chance of being given each treatment.

The following measurements will be monitored during your surgical procedure after the use of the induction medication blood pressure, mean arterial pressure, heart rate, pain on injection, and any muscle movements.

After you come out of the OR, we will collect information about any incidences of nausea, pain, and adverse events up to 24 hours after you receive the induction agent. This information will already be asked of you as a normal part of your care, therefore we will collect this information through your medical record.

What happens if I do not want to be in this research?

You may decide not to take part in the research and it will not be held against you. There would be no changes in the care that you receive during your surgical procedure if you decide not to participate.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you. Taking part in this study is your choice and completely voluntary. If you decide to take part in this study, you can decide to stop at any time. Leaving the study will not affect your medical care here at UC Davis. Tell the Researcher if you are thinking about stopping or decide to stop.

Is there any way being in this study could be bad for me?

You will be assigned to a study group at random (by chance). Your assignment is based on chance (like a coin flip) rather than a medical decision made by the researchers. The study group you are assigned to might not be the group you would prefer to be in. It might also prove to be less effective or have more side effects than the other study group, or standard treatments available for your condition. Below you can find the potential risks that the medications may pose.

Risks of Etomidate and Propofol

Risk of Etomidate:	**Frequency:**
Pain on injection	Very Common
Involuntary muscle movements	Common
Respiratory System: Shortness of breath, increased breathing; decreased breathing; hiccups, snoring	Common
Circulatory System: High blood pressure, low blood pressure, decreased heart rate; irregular heart rate	Common

Risks of Propofol:	**Frequency:**
Pain on Injection	Very Common
Cardiovascular: Decreased heart rate, increased heart rate, irregular heart rate, low blood pressure, decreased amount of blood pumped by heart	Common
Central nervous system: movement	Common
Metabolic/Nutritional: High amounts of fats/lipids in the blood	Common

Respiratory: Breathing temporarily stops, lungs cannot remove enough CO2 produced by body	Common
Skin and appendages: Rash, severe itching of the skin	Common

What happens to the information collected for the research?

Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB and other University of California representatives responsible for the management or oversight of this study.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your research records to conduct and oversee the study. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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.

If we access protected health information (e.g., your medical record), you will be asked to sign a separate form to give your permission. Your medical records may become part of the research record. If that happens, your research records may be looked at by the sponsor of this study and government agencies or other groups associated with the study. They may not copy or take your personal health information from your medical records unless permitted or required by law.

Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/compliance/pdf/notice.pdf) and in an attached document.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include difficultly securing your airway during surgery.

What else do I need to know?

There is no charge for you to participate in this study. Both medications area already routinely ordered and administered and will be billed accordingly to your insurance company.Your insurance company and or the sponsor/department will pay all costs associated with the study.

You or your health plan will be billed for the costs of routine medical care you receive during the study. These costs may include operating room fees, pharmacy charges, treatments, hospitalization, scans, etc. You will be expected to pay for the usual deductibles and co-payments, and for any routine care that is not covered. Only the costs of research or experimental procedures will be paid by the study.

For more information about possible costs, please contact the research team. The research team can follow UC Davis Uninsured Non-Emergency Estimate Policy (Policy ID 1883) to work with their department and Decision Support Services to get you a cost estimate.

You will not be compensated for taking part in this study.

It is important that you promptly tell the person in charge of the research if you believe that you have been injured because of taking part in this study. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about compensation, you may call the IRB Administration at (916) 703-9151 or email at HS-IRBAdmin@ucdavis.edu.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date
Printed name of person witnessing consent process	