Comparison between inhalational anesthetic (sevoflurane) and intravenous anesthetic (propofol infusion) for maintenance of sedation during Endoscopic retrograde cholangiopancreatography

Principle investigator
Dr. Vijai Kumar
Senior Lecturer

Department of Anesthesiology SIUT Karachi

Dated: 01-07-2021

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CONSENT FORM

I have been informed that I have Gastrointestinal disorder that will undergo certain tests like blood test, Ultrasound, Endoscopy that will help in diagnosis.

Endoscopy will be done under sedation to avoid distress during procedure.

I have been asked to participate in research study on Sedation during Endoscopy,in it two drugs will be used to compare their effects. One drug is Propofol and other drug is Sevoflurane. Both the drugs are commonly used for sedation during Endoscopy.

In this study Group A will receive propofol infusion that will be injected intravenously, and Group B will receive Sevoflurane that will be inhaled through nasal cannula.

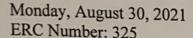
If you do not want to participate in research study than you will be given both drugs propofol and isoflurane, a third drug Ketamine may give if additional sedation is required because these are part of routine medicines used during endoscopy.

This research may be published in any local or international journal for medical purposes, but your identity will not be revealed.

Some of the side effects of these medicines sometimes seen in people, including decrease heart rate, decreased blood pressure, coughing, gagging, nausea and vomiting, all of these effects will be closely monitored and in the event of above incidents, it will be treated immediately with medicines and other measures.

If you have any question about this study at any time, you can contact the researcher at any time on the given number. Your participation in this study is completely voluntary. After signing the consent form, you are free to withdraw at any time and without giving a reason. If you give up this study, you will get the standard treatment you deserve in any case, there will be no change in your treatment.

Doctor/Researcher Name	
Signature	
Date	
Researcher Name and Contact no: <u>Dr Vijai Kumar :0333-7308228</u>	
Participant Signature	
Date:	
Name of the doctor taking consent	Witness Name
Signature	Signature
Date:	Date:



SIUT SINDH INSTITUTE OF UROLOGY AND TRANSPLANTATION

Approval No: SIUT-ERC-2021/A-325

Approval Issued: August 30, 2021

Vijay Kumar Department of Anesthesia, SIUT

Re: <u>Project Title "Comparison between inhalational anesthetic (sevoflurane) and intravenous anesthetic (propofol infusion) for maintenance of sedation during Endoscopic retrograde cholangiopancreatography."</u>

Dear Dr. Vijay Kumar,

Thank you for submitting the above referenced protocol to the SIUT-Ethical Review Committee (ERC). ERC finds that this protocol raises no ethical concerns. Approval is granted and you may commence your research. According to SIUT-ERC requirements, the ERC approval number should be clearly printed and visible on all consent forms used in the study.

Please note that this approval is valid for one year and relates to the ethical content of the study only. If you make any changes to the protocol during the period of this approval, you must submit a revised protocol to the SIUT-ERC for approval before implementing the changes.

SIUT-ERC requires a follow up from all researchers about the status of the approved research at the completion of one year from the date of issuance. You are also expected to comply with this practice.

Yours Sincerely,

Ali Lanewala, DABIM, DABP, DAB Nephrology Professor and In charge Pediatric Nephrology, Co-Chair, SIUT-Ethical Review Committee (SIUT-ERC)