27/11/2024

Sample Informed Consent Form

Informed Consent

Template for Creating an Informed Consent Letter

STUDY TITLE

EFFECT OF THE USE OF THE VENOUS EXCESS ULTRASOUND (VExUS) PROTOCOL ON PERIOPERATIVE FLUID MANAGEMENT, POSTOPERATIVE RESPIRATORY COMPLICATIONS, AND THE INCIDENCE OF POSTOPERATIVE ACUTE KIDNEY INJURY IN PATIENTS UNDERGOING THORACIC SURGERY

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TYPE OF STUDY

You are about to undergo a thoracoscopic procedure under general anesthesia. In such operations, it is recommended to limit the administration of intravenous fluids to reduce the risk of postoperative respiratory complications. However, restricting intravenous fluids may negatively affect kidney function. The VExUS ultrasound protocol is a non-invasive method for assessing fluid adequacy and can also indicate whether excessive fluids have been administered. The usefulness of this protocol in thoracoscopic procedures has not yet been determined, and this is the aim of the present study.

STUDY PURPOSE

You are invited to participate in a research study. Before deciding whether to take part, it is important to understand why the research is being conducted and what it will involve. Please read the following information carefully. Do not hesitate to ask the researcher about anything that is unclear or for any additional information you may need. The aim of this study is to investigate the effect of the VExUS ultrasound protocol on fluid management within the context of goal-directed therapy, on postoperative respiratory complications, and on the incidence of acute kidney injury in patients undergoing thoracic surgery.

WHY YOU HAVE BEEN INVITED TO PARTICIPATE

You have been invited to participate because the surgery you are scheduled to undergo is associated with possible complications affecting both the respiratory system and kidney function.

STUDY PROCEDURES

Your preoperative assessment will be conducted according to the standard hospital protocol. Intraoperative management will follow the usual clinical protocols. If you are randomized to the study group, you will undergo ultrasound assessment following the VExUS protocol immediately before anesthesia induction, after intubation, at the end of the surgery, and during your stay in the Post-Anesthesia Care Unit (PACU). The results will guide intravenous fluid administration.

POSTOPERATIVE PERIOD

After surgery, you will be transferred to the Post-Anesthesia Care Unit (PACU), where you will be monitored until your condition stabilizes. If you have been randomized to the study group, a repeat VExUS ultrasound will be performed in the PACU. Based on the ultrasound findings, up to 500 ml of intravenous fluids or diuretic therapy may be administered, followed by reassessment.

MEASUREMENTS

A. Postoperative Respiratory Complications

To assess oxygenation in both study groups, arterial blood gas samples will be collected preoperatively (for baseline PaO■ and PaCO■ values) and postoperatively in the PACU, on the 1st and 3rd postoperative days. You will be monitored daily for postoperative respiratory complications as defined by the European Society of Anaesthesiology. Additionally, to better assess the occurrence of atelectasis, pleural effusion, etc., a lung ultrasound will be performed on the 3rd postoperative day and prior to hospital discharge.

B. Postoperative Kidney Injury

To assess possible kidney injury, blood and urine tests will be conducted to measure biomarkers of renal function. eGFR will be calculated preoperatively and postoperatively in the PACU, on the 1st and 3rd postoperative days, based on serum creatinine levels. Furthermore, the following kidney injury markers will be measured: serum and urine cystatin C, urine total protein and albumin, urine creatinine, and urinary stress biomarkers TIMP-2 and IGFBP7, measured immediately postoperatively in the PACU and during your hospitalization. Finally, a follow-up laboratory test (serum creatinine and urea) will be recommended one month after surgery.

STUDY DURATION

Your participation in the study will last for the duration of your hospital stay before and after surgery.

RISKS

There are no risks associated with your participation, as aside from the VExUS ultrasound protocol (a non-invasive method) and blood sampling, the management will not deviate from standard care for thoracic surgeries.

BENEFITS

You will not receive any direct (financial or other) benefit from participating in this study. However, we believe that the information gathered—including your contribution—may demonstrate that the VExUS protocol can help optimize patient outcomes.

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CONFIDENTIALITY

Your participation in this study will remain anonymous. Researchers will make every effort to protect your privacy and confidentiality by using coded/anonymous identifiers and secure storage. Participant data will be treated confidentially, except where disclosure is required by law.

CONTACT INFORMATION REGARDING THE STUDY

If you have any questions about the study at any time, or experience any side effects, you may contact the researcher listed on the first page. For questions regarding your rights as a participant, you may contact the Ethics Committee – Scientific Committee of the University Hospital of Heraklion at +30 2810 392478.

VOLUNTARY PARTICIPATION

Your participation is entirely voluntary. You may withdraw at any time without providing justification or facing any consequences. Withdrawal will not affect your relationship with the researcher or healthcare provider. If you withdraw before the study ends, your data will be destroyed or returned.

STATEMENT OF CONSENT TO PARTICIPATE IN THE STUDY

I have read and understood the information provided above. I have had the opportunity to ask questions. I understand that participation is voluntary and I can withdraw at any time without consequences. I will receive a copy of this form. I voluntarily agree to participate in this study.

Participant's Signature: _____ Date: _____

Researcher's Signature: _____ Date: _____

Participant's Initials: _____