

INFORMED VOLUNTARY CONSENT FORM

COMPARISON OF DOUBLE LUMEN TUBE LOCATION CONFIRMATION TECHNIQUES IN SINGLE LUNG VENTILATION: AUSCULTATION, FIBEROPTIC BRONCHOSCOPY, VIDEO DOUBLE LUMEN TUBE

You are invited to our research study titled Comparison of Double Lumen Tube Location Verification Techniques in Single Lung Ventilation: Auscultation, Fiberoptic Bronchoscopy, Video Double Lumen Tube. 93 patients who will undergo surgery at Kayseri City Hospital and need to have a double lumen tube placed in the trachea under general anesthesia will be accepted to our study.

A double lumen tube will be placed in the trachea under general anesthesia for respiratory support during the surgical procedure to be performed. While one lung is deflated with the double lumen tube, the other lung continues to be ventilated. While the surgical procedure can be easily applied to the deflated lung, the body's oxygen needs are provided with the ventilated lung. In order to verify the location of the double lumen tube, we plan to compare the methods used in our hospital such as listening to lung sounds with a stethoscope, fiberoptic bronchoscopy (a device that provides images with a camera and light system), and video double lumen tube (a tube with its own camera and light system).

The volunteers included in the study will be divided into three groups. The groups of the volunteers will be randomly determined. You will not know which group you are in. An experienced anesthesiologist will perform the tube placement in the volunteers' trachea. The anesthesiologist who will perform the procedure will know your group. The first group will be using a traditional double-lumen tube found in our hospital. After the tube is placed in the trachea, the tube location will be verified by listening to breath sounds with a stethoscope and verifying that the tip of the tube is in the left lung. The second group will be using a traditional double-lumen tube found in our hospital. After the tube is placed in the trachea, the tube location will be verified by seeing that the tip of the tube enters the left lung with a device called Fiberoptic Bronchoscopy, which has its own camera, screen and light system. The third group will be using a video double-lumen tube (tube with its own screen, camera and light system) found in our hospital under general anesthesia and verifying that the tip of the tube enters the left lung with a camera on the screen.

We aim to shorten the tube location verification time by investigating the superiority of these methods over each other, to prevent damage that may arise from tube placement disorders, and to investigate the most cost-effective method.

If difficult airway management is encountered after general anesthesia is administered in the operating room, you will be excluded from the study. There will be no change in your treatment if you are excluded from the study.

In this regard, we request your permission to include you in our research. You are free to participate in this research or not. We would like to inform you about our research before you make your decision. If you want to participate in the research after reading and understanding this information, please sign the form. The evaluation of the double lumen tube location verification techniques to be examined in the study will be carried out in the Kayseri City Hospital operating room. If you give permission, your records will be evaluated anonymously and a report will be prepared. Information regarding the test/questionnaire results will be stored only in the records of the project manager Dr. Çiğdem Ünal Kantekin, and in this way, your information will be kept completely confidential. Records obtained from this study that will reveal the identity of the volunteer will be kept confidential and will not be disclosed to the public; even if the research results are published in medical journals, the identity of the volunteer will remain confidential. Even if the information

Date	Version No	Page	Researcher Initials	Volunteer Initial
04.11.2024	02	1/3		

INFORMED VOLUNTARY CONSENT FORM

obtained from this study is published in medical journals, patient names will not be included. You will not be charged for participating in this study. You will not be paid for participating in the study.

Volunteers will be informed when new information is obtained regarding the research topic that may affect the volunteer's desire to continue participating in the study.

Possible risks of the research to be conducted:

Our study is an observational recording study. Routine anesthesia will be performed by anesthesiologists who are independent of the study. The conductors of the study will only observe the procedure, so there is no risk of the study. It does not pose any additional risks to the surgery and anesthesia to be performed.

Possible benefits of the research to be conducted:

By comparing double-lumen tube location verification techniques with this study; the tube location verification time can be shortened, damages that may arise from tube placement disorders can be reduced, and the new data obtained can shed light on new studies to be conducted on this subject.

You may refuse to participate in this study. Participation in this study is completely voluntary. You may refuse to participate in the study or withdraw from the study at any time, without being subject to any penalty or sanction, and without losing any of your rights. There will be no change in the treatment applied to you if you refuse to participate in the study or withdraw from the study. You also have the right to withdraw your consent at any stage of the study.

Your medical information will be kept confidential, however, the staff who monitor the quality of the study, the monitors, the people who conduct the examination, the ethics committee, the institution and other health authorities will have direct access to the original medical records of the volunteers if necessary, but this information will be kept confidential. By signing the voluntary consent form, you will have given permission for such access.

(Volunteer Declaration)

“I have read all the explanations in the Informed Volunteer Consent Form. After this information, I was invited to such a research as a “participant” by Dr. Çiğdem Ünal Kantekin. The written and verbal explanation regarding the research, the subject and purpose of which were specified to me, was made by Dr. Çiğdem Ünal Kantekin. I know that I am participating in the research voluntarily, that I can withdraw from the research at any time with or without a reason, and that I can be excluded from the research by the researcher regardless of my own will.”

“I agree to participate in the research in question, without any pressure or coercion, of my own free will.”

If I participate in this research, I believe that the confidentiality of my information, which should remain between me and the physician, will be treated with great care and respect during this research.

I have been given sufficient confidence that my personal information will be meticulously protected during the use of the research results for educational and scientific purposes.

I may withdraw from the research without giving any reason during the implementation of the project. (However, I am aware that it would be appropriate to notify the researchers in advance that I will withdraw from the research in order not to put them in a difficult situation.) In addition, I may be excluded from the research by the researcher, provided that no harm is done to my medical condition. I do not assume any financial responsibility for the expenses to be incurred for the research. No payment will be made to me either.

Date	Version No	Page	Researcher Initials	Volunteer Initial
04.11.2024	02	2/3		

INFORMED VOLUNTARY CONSENT FORM

I have been given the necessary assurance that any kind of medical intervention will be provided in case of any health problem that may arise due to reasons arising from the research application, whether directly or indirectly. (I will not undertake any financial burden regarding these medical interventions).

If I encounter a health problem during the research; I know which researcher I can call at any time of the day (24/7 during the research period), at which phone number and address.

Doctor's Name - Surname: Dr. Çiğdem Ünal Kantekin

Work Phone: 03523157700 **Mobile Phone:** 05054433056

I am not obliged to participate in this research and I may not participate. I have not encountered any coercive behavior regarding my participation in the research. I also know that if I refuse to participate, this will not harm my medical care or my relationship with the physician. I have understood all the explanations given to me in detail. After a certain period of thinking on my own, I have decided to take part in this research project as a "participant". I accept this invitation with great pleasure and voluntarily, of my own free will.

A copy of this signed form will be given to me.

Volunteer	
Name Surname	
Address	
Contact Number	
Date	

Signature

Responsible Researcher	
Name Surname	
Address	
Contact Number	
Date	

Signature

Date	Version No	Page	Researcher Initials	Volunteer Initial
04.11.2024	02	3/3		