VideolaryngoscOpy with McGrath vs direct LaryngosCopy for the positioning of A double lumeN endOtracheal tube (VOLCANO Study)

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Dear patient/legal guardian of the patient,

We are conducting a randomized controlled study on the use of Videolaryngoscopy in the double-lumen tube (DLT) intubation procedure for surgeries requiring one-lung ventilation (OLV).

This international study is approved in our center by the Ethics Committee of the A.O.U. Città della Salute e della Scienza in Torino.

The superiority of videolaryngoscopy (VLS) over direct laryngoscopy (DL) is clear regarding the placement of single-lumen endotracheal tube (SLT). DLT placement can be more challenging as the endobronchial tube is larger and more rigid. Success rate and intubation time can vary greatly during DLT placement.

19 studies have reported the efficacy of six videolaryngoscopes for DLT intubation compared to the direct laryngoscope in patients with anticipated non-difficult airways. Except for videolaryngoscopy potentially providing a better glottic view than the direct laryngoscope, other results have not been consistent across different studies. Conducting a study with adequate/larger sample size compared to previous studies and homogeneous population can ascertain whether VLS, like in the case of SLT, can provide added value in DLT placement, guiding clinicians towards its routine use. It is also noted that current guidelines on DLT intubation do not recommend VLS use as "1st choice," as is the case for SLT. For this reason, both devices are practically used interchangeably in clinical practice, essentially based on individual clinician preferences, who possess comparable expertise in both direct laryngoscopy and videolaryngoscopy.

The purpose of the study is to compare the efficacy of videolaryngoscopy vs direct laryngoscopy in double-lumen tube placement in surgery with the aim of increasing first-attempt placement success and reducing the incidence of DLT misplacement with DL, reducing intubation time, and intubation difficulty scoring with VLS.

Participation in the study is spontaneous and voluntary. This means that the patient will be enrolled as a participant only after obtaining written consent. In case of refusal to participate in the study, at the time of information as well as subsequently, there will be no consequences.

The medical staff has already presented to you the possibility of participating in the study. The following text aims to clarify its purpose and conduct, as well as to outline the patient's rights regarding potential participation. Afterward, you can have a discussion with the study-dedicated medical staff. Please feel free to ask questions about all the points outlined below if they are unclear. You will be given sufficient time to reflect and consider the possibility of participating in the study.

How is the study conducted, and what does it entail for my condition?

IMPORTANT: Participation in the study will not influence in any way either clinical decisions or the appropriate therapeutic plan for your clinical condition. The treatment and care reserved for you remain unchanged. Simply, the clinical course is observed, and the related data are collected. However, you may still decide to discontinue participation in the study at any time, without the need to provide a reason, and without any repercussions on the therapeutic measures formulated.

All data collected for observational purposes are already part of the daily and routine medical records, and for the purposes of the said study, they will be stored in dedicated anonymous databases.

What benefits do I gain from participating in the study?

Participating in the study will not result in any changes to the therapy set in light of your clinical condition. By participating in the study, you can contribute to obtaining new important results that may improve intubation techniques and airway management in the future.

What risks are associated with participating in the study?

No additional risks are associated with participating in the study.

Does participation in the study incur any expenses?

Participation in the study does not incur any costs, nor does it involve any reimbursement or compensation.

Am I insured during participation in the study?

During participation in the study, the patient is insured as per the safety standards throughout the entire hospital. Additional insurance is not necessary within the scope of this study.

Will I be informed of the study results related to the clinical condition?

During participation in the study, you will be informed of any results derived from data analysis that are also relevant to the continuation of your participation in the study. Based on these findings, you will be able to make further decisions regarding the possible continuation of your contribution to the study.

Who decides to discontinue participation in the study?

Participation in the study is voluntary, subject to written consent signed by you. However, you may decide to discontinue participation in the study at any time, without the need to provide a reason, and without any repercussions on the therapeutic measures formulated for you.

In particular circumstances, it is also possible for the research team to discontinue the patient's participation in the study without the patient being able to object to this decision.

Possible reasons include:

- Your participation in the study is no longer sustainable for clinical reasons;
- The entire study is discontinued.

I _____ born in _____ on _____ address

_____ phone number _____

on my own behalf

through a legal guardian/administrator of support Mr./Ms. _____

DECLARE

To voluntarily participate in the study " VideolaryngoscOpy with McGrath vs direct LaryngosCopy for the positioning of A double lumeN endOtracheal tube" conducted at Department of Anesthesia and Intensive Care 1U - A.O.U. Città della Salute e della Scienza, P.O. Molinette Corso Bramante 88-90, 10126 Turin, Italy.

To have received from Dr. _____ comprehensive explanations regarding the request for participation in the research, particularly on the objectives and procedures; I have been informed by the medical staff that the care strategy under which my clinical situation was managed (of which severity and therapeutic characteristics I have been clearly informed) is part of a research project, approved by the Competent Interagency Ethics Committee. It is a prospective, non-pharmacological study. The evaluation of the data and results of this study is necessary to produce new knowledge useful for evaluating the effectiveness of dedicated devices for intubation with double-lumen tube (DLT) in procedures requiring one-lung ventilation (OLV).

To have had enough time to read carefully, understand, and possibly have explained what is contained in the attached information sheet confirming what has been explained to me verbally, especially that the experimentation will be conducted in compliance with International Ethical Codes.

To have had the opportunity to ask questions and have received satisfactory answers regarding the entire experimentation and in particular on the consequences of not performing the proposed procedure.

To be informed about the possible foreseeable risks or discomforts.

To consent to monitoring, auditing, national and foreign regulatory authorities having direct access to my medical documentation for monitoring and verification purposes.

To be aware that participation is voluntary, with the assurance that refusal to participate will not affect receiving the most suitable treatment.

To be aware that data will be processed in full compliance with existing legislation regarding respect for confidentiality and personal rights (under the EU Regulation 2016/679 General Data Protection Regulation - GDPR - concerning the protection of individuals with regard to the processing of personal data, as well as the free movement of such data).

To be aware:

- that I may withdraw from the experimentation already underway at any time, without negative consequences in receiving the most appropriate treatment and without the obligation on my part to justify the decision, unless it results from the appearance of unforeseen and/or unintended disturbances or side effects, in which case I commit from now on to promptly inform the experimenting physician of nature and extent;
- that the medical record will remain strictly confidential and data will be used for the purposes indicated in the study;
- that the use of my clinical data will occur according to the methods and criteria of the protocol, and in the form of anonymization approved by the Competent Ethics Committee;

- that I will be informed of any new data that may affect the risks or benefits, or of protocol variations that may affect them;
- that it is my right to access the documentation concerning me and the evaluation expressed by the Ethics Committee to which I may turn if I deem it appropriate;
- that a copy of the informed consent and the documentation I have reviewed will remain in my possession;

Therefore, I confirm that I have had comprehensive answers to all my questions and, having taken note of the situation outlined,

I CONSENT

TO PARTICIPATE IN THE EXPERIMENTATION PROPOSED TO ME.

I also declare to be aware of the possibility of revoking this consent at any time.

Patient's/legal representative's signature: _____

Doctor’s name:_____

Doctor's signature: _____

OR

The patient expresses verbal consent and freely, spontaneously, and fully awarely consents to the experimentation proposed to him/her.

Doctor’s name: _____

Doctor's signature: _____

Any witnesses present (name, surname, signature):_____

Date: _____

I DO NOT CONSENT

TO PARTICIPATE IN THE EXPERIMENTATION PROPOSED TO ME.

I also declare to be aware of the possibility of revoking this consent at any time.

Patient's/legal representative's signature: _____

Name of the doctor:_____

Doctor's signature: _____

OR

The patient verbally expresses, freely, spontaneously, and fully awarely, his dissent to the proposed experimentation

Doctor’s name: _____

Doctor's signature: _____

Any witnesses present (name, surname, signature):_____

Date: _____