This submission includes:

1. Informed consent

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1. **Informed Consent**

Project title: Estimation of the non-inferiority of the Laringocel® videolaryngoscope versus the C-MAC D-BLADE (Karl Storz®) for first-attempt intubation in adult patients scheduled for elective surgery: Protocol for a randomized non-inferiority clinical trial. **LARINGOCOL**

Principal Investigator details
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Institutions supporting the research: Universidad de Antioquia – Hospital Alma Máter de Antioquia

Entity sponsoring the research: None

Study Information

Justification and objectives

Dear participant: You have been invited to take part in this research because you will undergo a surgical procedure and, as part of routine anesthetic management, you require placement of a breathing tube through the mouth that will be positioned in your airway (called orotracheal intubation).

This study seeks to compare two existing medical devices, which are used routinely, that assist with orotracheal intubation. These devices are called videolaryngoscopes and, through a camera, allow visualization of the airway at the moment the tube is inserted, which can increase the likelihood of successful intubation. One of the most widely used videolaryngoscopes worldwide is the C-MAC (German), which is costly to acquire and maintain. The other device was developed by Colombian researchers, the Laringocel, which is less expensive, easier to acquire, and already has INVIMA approval for use.

The objective of the study is to determine whether the national device is acceptable compared with the international device. This could facilitate access to high-quality devices in resource-limited settings.

Benefits for the participating patient

If you participate, intubation will be performed using videolaryngoscopy devices, which are state-of-the-art equipment designed to facilitate the procedure and increase the probability of successful first-attempt intubation. This may reduce risks such as requiring multiple attempts or procedure failure.
In addition, intubation will be performed exclusively by an experienced anesthesiology specialist and not by trainees, which provides an added benefit in terms of safety and confidence and mitigates potential risk.
Furthermore, your participation will contribute to science and health care in Colombia. The information obtained in this study will help improve access to quality devices in Medellín and nationwide, benefiting future patients who require this procedure.

Study procedures

After agreeing to participate in the research, you will be randomly assigned to one of the two study groups; you have an equal probability—like heads or tails in a coin toss—of being in the group intubated with the Laringocel or the C-MAC videolaryngoscope. The result regarding the group to which you were assigned will be concealed in an envelope and will only be known once the envelope is opened and orotracheal intubation is performed with the assigned device.
During the procedure, the anesthesiologist will perform orotracheal intubation using the previously assigned device, once your adequate preparation has been verified. Up to three attempts will be allowed with that device; however, the study does not prevent the anesthesiologist from changing equipment if they consider it safest for the patient. In all cases, the anesthesiologist will have an alternative laryngoscope as a rescue device, which minimizes risks and protects participant safety.
Additionally, a video recording will be made of the passage of the tube through the airway, which will be reviewed later by an independent investigator who will not know which group the patient was assigned to. This recording will be used solely for scientific purposes to evaluate device performance.
After the surgical procedure, once the tube has been removed, your oral cavity will be examined and you will be asked one question. This evaluation will take approximately 5 minutes.
Participation in the study does not modify the standard intubation procedure. The anesthesiologist who performs the anesthetic act is not part of the research team.
Your participation in this study is completely voluntary, and you may withdraw at any time. The data or any information obtained from you, such as your name, ID number, age, and other information collected by the investigators, will be concealed from anyone not involved in the research; that is, it will be kept strictly confidential.

Participation does not entail any additional costs for you other than the time involved, which we expect to be only a few minutes.

Total study duration and duration of subject participation
The total duration of the research is set at twelve months. However, your participation consists of a short period of approximately 15 minutes, including the initial evaluation, the intubation, and the subsequent evaluation, which will be performed approximately one hour after extubation (when the tube is removed), at which point your participation in the research will end. A total of 252 people are expected to participate.

Duration, frequency, and location of procedures
For research purposes, the intubation process will be performed once during anesthesia for your surgery, in the operating rooms of Hospital Alma Máter de Antioquia. The post-intubation evaluation will be performed in the post-anesthesia recovery room or in the corresponding care unit.

Research risks
The risks involved are the same as those of the usual orotracheal intubation procedure, including possible sore throat, oral or pharyngeal mucosal injury, and dental loss, which are infrequent events. Should they occur, they will be managed in continuity with your usual medical care.

Alternative procedures
Both devices evaluated in the study are used routinely. If the assigned device does not allow successful intubation, another device or alternative strategy will be used according to the anesthesiologist’s decision.

Assurance of response to questions:
You may ask any questions related to the study before, during, or after your participation, and these will be answered promptly by the research team.

Freedom to withdraw informed consent:
You may withdraw from the study at any time, without this affecting the quality of the medical care you will receive.

Aspects for ending participation in the research:
Your participation in the research will end once all study data have been collected

when the post-extubation evaluation is completed, or if you decide to withdraw at any time.

Privacy:
The information collected will be handled confidentially. Procedure videos will be stored securely and will not include information that could identify you. Results will be published while safeguarding each participant's confidentiality.

Medical treatment:
During your participation in this study, **no** aspect of your current medical treatment or your hospitalization in hospital services will be modified. You will continue to receive standard care as determined by your medical team.

Additional costs:
You will not incur additional expenses for participating in this study, other than your time, which we expect to be brief. The costs of the procedure are part of routine clinical management.

Authorization for data use:
You authorize the use of the information collected during this study **exclusively** for scientific research purposes. No biological samples will be collected. The data may also be used for related future research, always ensuring confidentiality and only if you provide authorization for such use.

Expected results
We expect the results of this study to help optimize the selection of videolaryngoscopes in resource-limited settings. In addition, we aim to present these results at medical conferences and publish them in scientific journals so that students, physicians, and professors in different parts of the world—especially in Colombia—can pursue intubation management based on the best devices available.

Participant commitments
1. Inform any of the investigators or the Ethics Committee of Hospital Alma Máter de Antioquia of any harm or adverse event that may occur.

Investigator commitments
1. Provide follow-up during and 1 hour after extubation.
2. Be attentive to and resolve any problems that arise during the study period.

3. Facilitate, if necessary, connection with the specialists or support you require, ensuring continuity of your care.
4. Safeguard at all times the protection of your health, dignity, integrity, right to self-determination, privacy, and confidentiality.
5. Renew and update this Informed Consent document if changes to the protocol occur or if new risks are identified during the conduct of the study.
6. The research has been duly approved by the Bioethics Committee of Hospital Alma Máter de Antioquia. Any new version of the Informed Consent will be submitted to the Ethics Committee for review and approval before being implemented. The investigators are physicians who graduated from accredited universities and hold current licenses to practice.
7. Respond clearly, truthfully, and promptly to all questions that you or the Ethics Committee may have about the study.
8. Disclose the research results once the study is concluded.
9. Provide real-time information on the status of the study.

Signing this document does not imply the waiver of any legal rights to which you are entitled. It is hereby certified that a copy of this document will be provided to the participant.

Contacts for information

Principal Investigator: Gabriel Ricardo Muñoz Miranda. Address: Diagonal 67 #31–235, Bello, Antioquia. Phone numbers: 3187162895 – 3166364654. Email: gabrielr.munozm@udea.edu.co.

Contact — Research Ethics Committee of Hospital Alma Máter

If you have any remaining questions or concerns about your rights as a research participant, you may contact the Research Ethics Committee of Hospital Alma Máter de Antioquia, address: Calle 69 # 51C – 24, Building 2, 2nd floor, Office 206; phone: 604 9595, extension 32109; email: cei@almamater.hospital.

Acceptance of participation in the study

I, _____, identified with national ID number _____ issued in _____, confirm that I have read and have been given a detailed explanation of the information related to this study, and that I have had the opportunity to ask questions, which have been answered to my satisfaction.

I state that I have not received verbal, written, and/or gestural pressure to participate in the study; that I made this decision in full possession of my mental faculties, not under the influence of medications, drugs, or alcoholic beverages, consciously, autonomously, and freely.

I understand that my participation is voluntary and that I may withdraw at any time, without needing to justify my decision, and without affecting my legal rights or the quality of the medical care I receive.
Accordingly, I choose (mark with an X):

☐ I agree to participate in the study described above.

☐ I agree that my information will be stored confidentially and used in subsequent academic studies.

☐ I do not agree to participate in the study described above, nor that my information be used in the current or future research.

Signature: _____
Date: _____
Time: _____

Principal investigator or person obtaining consent:
Name:
Signature: _____
Date:

Witness 1
Name:
Relationship to the participant:
Home address:
Signature: _____
Date:

Witness 2
Name:
Relationship to the participant:
Home address:
Signature: _____
Date: