PATIENT INFORMATION SHEET AND INFORMED CONSENT FORM

Field	Information
Study title	Effect of Body Mass Index-Adjusted Positive End-Expiratory Pressure on Respiratory Mechanics During One-Lung Ventilation in Thoracic Surgery
Study type	Prospective, multicenter, 1:1 randomized, pragmatic, open-label, parallel-group clinical trial, with blinded assessment of postoperative outcomes.
Sponsor/Investigator	Dr. Jesús Manuel Nieves Alonso
Coordinating center	Hospital Universitario de La Princesa, Madrid
Principal Investigator of the study	Dr. Jesús Manuel Nieves Alonso
Site Principal Investigator	
Site	
Version and date	Version 3.0, 29 August 2026

Dear Participant:

You are invited to take part in a research study because you are scheduled to undergo elective pulmonary resection surgery under general anesthesia, and one lung will need to be ventilated during part of the procedure. This document provides information to help you decide whether you wish to participate.

Please read it carefully. You may ask the study doctor or study staff any questions before signing. Do not sign this document until you have understood the information and received satisfactory answers to your questions.

The study has been reviewed and received a favorable opinion from the relevant Research Ethics Committee for Medicinal Products (CEIm) before patient recruitment begins.

1. Background

During thoracic surgery, it is often necessary to ventilate only one lung while the lung being operated on remains collapsed to allow the surgery to be performed. This situation, known as one-lung ventilation, may lead to poorly ventilated areas of lung, changes in oxygenation, and alterations in respiratory mechanics.

To reduce these problems, lung-protective ventilation strategies are used during anesthesia. These strategies include tidal volumes adjusted to the patient's size, limitation of airway pressures, and the application of positive end-expiratory pressure, known as PEEP, which aims to reduce collapse of the ventilated lung.

The optimal level of PEEP during one-lung ventilation has not been fully established. In clinical practice, different strategies are used, ranging from conventional PEEP applied similarly to most patients to individualized PEEP adjustment. Body mass index (BMI) is a simple measure available before anesthesia that may be related to respiratory mechanics. This study therefore evaluates whether adjusting PEEP according to BMI improves respiratory mechanics during one-lung ventilation.

2. What is the purpose of the study?

The primary aim of the study is to determine whether a PEEP (positive end-expiratory pressure) strategy adjusted according to BMI improves respiratory mechanics during one-lung ventilation compared with usual clinical practice using conventional lung-protective ventilation with conventional PEEP.

To do this, variables such as respiratory system compliance, driving pressure, airway pressures (which reflect the quality and safety of ventilation), oxygenation, the need for rescue maneuvers for hypoxemia (low blood oxygen), and postoperative outcomes will be assessed. Driving pressure is a measure that relates the volume delivered by the ventilator to the pressure required to ventilate the lung; in general, lower values are considered more favorable in terms of respiratory mechanics.

3. Why have you been asked to participate?

You have been asked to participate because you are an adult scheduled for thoracic surgery requiring general anesthesia and one-lung ventilation. Before enrollment, the study team will check that you meet the study criteria and that there is no reason why participation would be inadvisable.

Approximately 150 patients are expected to be included in total across several participating hospitals in Spain.

4. What does participation involve?

If you agree to participate and meet the study criteria, you will be randomly assigned, by chance, to one of the two study groups. Allocation will be 1:1, so you will have approximately a 50% chance of being included in either group:

- Control group: lung-protective ventilation with conventional PEEP according to usual clinical practice; PEEP = 4 cmH_2O.
- Experimental group: lung-protective ventilation with BMI-adjusted PEEP, calculated approximately as BMI/3 cmH_2O (your BMI divided by 3 will determine the prescribed PEEP), applied after induction of anesthesia and during one-lung ventilation according to the study protocol.

Both strategies fall within the framework of lung-protective ventilation used in routine clinical practice. As an additional safety measure, the PEEP assigned to the experimental group will be limited to a range of 4 to 15 cmH_2O during the study.

During anesthesia, information related to the procedure, ventilator settings, respiratory mechanics, oxygenation, and hemodynamic status will be collected. Results of tests performed as part of routine care, such as arterial blood gases, laboratory tests, X-rays, or other clinically indicated investigations, may also be recorded.

After surgery, your clinical course will be reviewed to assess possible pulmonary complications or other postoperative events, the need for respiratory support, admission to the post-anesthesia care/recovery unit or postoperative intensive care unit (ICU), length of hospital stay, and other clinical information related to the procedure. Data will be collected from your medical record and routine clinical care.

5. Will any additional tests be performed?

No additional invasive tests are planned solely because you are taking part in the study. Anesthetic monitoring, mechanical ventilation, hemodynamic treatment, and complementary tests will be performed according to medical judgment and usual practice in thoracic surgery. No biological samples are planned to be stored for future analyses.

6. Possible risks and discomfort

Participation in this study is not expected to involve relevant risks beyond those associated with general anesthesia and thoracic surgery with one-lung ventilation.

PEEP is part of routine mechanical ventilation during anesthesia. In some patients, certain ventilator settings may be associated with changes in blood pressure, oxygenation, or airway pressures. These situations are familiar to the anesthesia team and will be treated immediately according to usual clinical practice, by adjusting ventilation, administering fluids, vasopressors, or other measures as necessary.

If hypoxemia (low blood oxygen) or another clinical situation requiring intervention occurs during surgery, the anesthesiologist may modify the ventilator settings and apply rescue maneuvers regardless of the assigned group. Patient safety will always take priority over the study protocol.

7. Expected benefits

We cannot guarantee that you will obtain a direct benefit from taking part in the study. The BMI-adjusted strategy may improve some respiratory parameters during surgery, but this is precisely what the study aims to determine. Your participation may help improve our understanding of how to adjust mechanical ventilation during thoracic surgery and may contribute to improving the care of future patients.

8. Voluntary participation and withdrawal from the study

Your participation is entirely voluntary. You may decide not to participate without this affecting the quality of the medical care you receive or your relationship with healthcare professionals.

You may also withdraw your consent at any time, without giving a reason and without this affecting your medical care. If you withdraw, you may indicate that no new data should be collected from that point onward. Data collected before withdrawal may continue to be used in pseudonymized form when necessary to preserve the scientific validity of the study, in accordance with applicable regulations and the instructions of the Ethics Committee.

9. Alternatives to participation

The alternative to taking part in this study is to receive anesthesia and mechanical ventilation according to the usual practice of your center, without random allocation and without study-specific data collection for this project.

10. Ethical considerations

The study will be conducted in accordance with the ethical requirements of the World Medical Association Declaration of Helsinki, as adopted in its most recent version at the 75th General Assembly (Helsinki, Finland, October 2024) for research involving human participants, and Spanish Law 14/2007 of 3 July on Biomedical Research. The study protocol, this Patient Information Sheet, and the Informed Consent Form were submitted for review and approved by the CEIm of Hospital de La Princesa before recruitment begins.

Copies of the Declaration of Helsinki and subsequent amendments may be obtained through the World Medical Association website (www.wma.net).

In accordance with the International Ethical Guidelines for Health-related Research Involving Humans of the Council for International Organizations of Medical Sciences (CIOMS, Geneva, 2016), and the recommendations of the Spanish Society of Epidemiology (SEE) regarding ethical review of epidemiological research, this study was submitted to and approved by the CEIm of Hospital de La Princesa.

11. Confidentiality and data protection

Personal data will be processed in strict compliance with Regulation (EU) 2016/679, the General Data Protection Regulation (GDPR), and Spanish Organic Law 3/2018 of 5 December on Personal Data Protection and Guarantee of Digital Rights (LOPDGDD). The Principal Investigator undertakes to maintain the confidentiality of the information and to use the data exclusively for the purposes specified in this protocol.

Data will be collected in pseudonymized form using a study code. This means that investigators analyzing the data will not work directly with your name or other identifying information. The link between the study code and your identity will be kept securely at the participating center and will be accessible only to authorized personnel when necessary.

If necessary, and always subject to confidentiality obligations, the original information may be accessed by the authorized study team, study monitors or auditors, the Ethics Committee, competent health authorities, and other persons or institutions authorized by applicable regulations to verify that the study is being conducted correctly.

In accordance with the Seventeenth Additional Provision of the LOPDGDD, the following safeguards are guaranteed:

- Access to the data is limited to the Principal Investigator and the authorized collaborating team.
- The necessary technical security measures have been implemented to prevent unauthorized access or loss of information integrity.
- Study results will be presented in aggregate form, ensuring that no publication or report allows individual participants to be identified.

Where applicable, you may exercise your rights of access, rectification, erasure, objection, restriction of processing, and data portability. In health research, some of these rights may be restricted when exercising them could prevent or seriously hinder the objectives of the study, in accordance with applicable regulations. To exercise these rights, you may contact the Principal Investigator at your center or the institution's Data Protection Officer.

All documentation generated during the study will be treated as strictly confidential. Electronic study data will be stored in restricted-access systems protected by authentication and permission controls so that only authorized persons can access them. Clinical data will be kept in pseudonymized form, and the information that links your study code to your identity will be held separately at your center. Technical and organizational security measures required by applicable regulations and the policies of the participating institutions will be applied. These confidentiality obligations are of indefinite duration and apply to all collaborators involved in any phase of the project.

12. Insurance, compensation and liability coverage

The study is designed as a pragmatic, minimal-risk clinical trial comparing two lung-protective ventilation strategies used in routine clinical practice. Coverage for any harm arising from healthcare and, where applicable, from the study will be governed by applicable regulations and the liability insurance policy of the participating center.

13. Who can you contact if you have questions?

You may ask any questions about the study before signing the consent form and at any time during your participation.

Site Principal Investigator: _____.

Department: Anesthesiology and Resuscitation. Telephone: _____. Email: _____.

Data Protection Officer at the center: _____.

Telephone/email: _____.

14. Other relevant information

Taking part in this study will not involve any financial cost to you, and you will not receive financial compensation for participation. Participation will not change the indication for surgery, the anesthetic plan, or any treatment you may require according to medical judgment.

If new relevant information becomes available during the study that could affect your decision to continue participating, you will be informed when appropriate.

INFORMED CONSENT

Project title: Effect of Body Mass Index-Adjusted Positive End-Expiratory Pressure on Respiratory Mechanics During One-Lung Ventilation in Thoracic Surgery.

Principal Investigator of the study: Dr. Jesús Manuel Nieves Alonso.

Center: _____. Department: Anesthesiology and Resuscitation.

Study code: _____. Document version: 3.0, 29 August 2026.

I, Mr./Ms. _____, declare that:

- I have read the Patient Information Sheet provided to me.
- I have had the opportunity to ask questions about the study.
- I have received satisfactory answers to my questions.
- I have received sufficient information about the study.
- I understand that my participation is voluntary.
- I understand that I may withdraw from the study at any time, without giving a reason and without this affecting my medical care.
- I understand that my data will be handled confidentially and in pseudonymized form in accordance with applicable data protection regulations.
- I understand that no additional invasive tests are planned and that no biological samples will be stored solely because of my participation in this study.
- I have received a copy of this document.

I hereby agree to participate in this study.

Participant signature	**Investigator signature**
Full name: _____	Full name: _____
National ID/Foreign Resident ID: _____	Professional registration no.: _____
Date and place: _____	Date and place: _____

REVOCATION OF CONSENT

I, Mr./Ms. _____, withdraw my consent to participate in this study. I understand that this decision will not affect my medical care.

Participant signature

Full name: _____

Date and place: _____

Investigator signature

Full name: _____

Date and place: _____