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Videolaryngoscopy versus direct laryngoscopy for tracheal intubation in paediatric surgery: the VIDEOKIDS pragmatic international multicentre randomised trial study protocol

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ABSTRACT

Introduction Tracheal intubation in paediatric patients is a fundamental procedure in anaesthesia practice. Failure to achieve successful intubation on the first attempt is associated with an increased risk of complications, including hypoxaemia and airway trauma. Videolaryngoscopy has been proposed to improve glottic visualisation and facilitate tracheal intubation; however, current evidence in paediatric patients remains inconsistent and largely derived from small or highly selected populations.

The purpose of this study is to compare successful intubation on the first attempt using videolaryngoscopy versus direct laryngoscopy during tracheal intubation in paediatric patients undergoing surgery. We hypothesise that videolaryngoscopy will increase the frequency of successful intubation on the first attempt.

Methods and analysis The VIDEOKIDS trial is a prospective, international, multicentre, open-label, randomised controlled trial designed to compare videolaryngoscopy with direct laryngoscopy for tracheal intubation in paediatric patients undergoing general anaesthesia. Eligible patients aged 0–16 years requiring orotracheal intubation for elective or urgent surgery will be randomly assigned in a 1:1 ratio to videolaryngoscopy or direct laryngoscopy for the first intubation attempt. The choice of device brand and peri-intubation management, including patient positioning, preoxygenation strategy and pharmacological agents, will be left to the discretion of the attending anaesthesiologist according to local practice. The primary outcome is successful tracheal intubation on the first attempt. Secondary outcomes include time to intubation, number of intubation attempts, glottic visualisation, need for adjunct airway devices and intubation-related complications. The primary analysis will follow the intention-to-treat principle and will be unadjusted. A mixed-effects logistic regression model will be used as a sensitivity analysis to account for centre-level variability and prespecified clinically relevant covariates, including age group.

The trial is expected to be conducted in approximately 20–25 hospitals across six countries: Spain, Portugal, Uruguay, Mexico, Colombia and Brazil. Enrolment began in May 2026 and is expected to be completed in December 2027.

Ethics and dissemination The study protocol was approved in March 2026 by the Ethics Committee of Galicia (CEImG, code No. 2026/168). The results of this trial will be disseminated through presentations at scientific conferences and publication in a peer-reviewed journal.

Trial registration number NCT07495436.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a prospective, international, multicentre, open-label, randomised controlled trial comparing videolaryngoscopy and direct laryngoscopy for tracheal intubation in approximately 5600 paediatric patients undergoing surgery.
⇒ The trial includes children across the full paediatric age range (0–16 years), with randomisation stratified by centre and by three prespecified age groups (<28 days, 28 days–1 year and >1–16 years).
⇒ The study will be conducted across approximately 20–25 hospitals in six countries with different healthcare systems and levels of healthcare expenditure, involving clinicians with varying levels of experience.
⇒ The nature of the study does not allow blinding clinicians to the allocated intervention.

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INTRODUCTION

Background and rationale

Tracheal intubation is a fundamental procedure in anaesthesia and critical care, routinely performed to secure the airway and ensure adequate ventilation. Achieving successful intubation on the first attempt is a key clinical objective, as multiple attempts are consistently associated with an increased risk of complications, including hypoxaemia, cardiovascular instability and airway trauma.[1 2]

Direct laryngoscopy has traditionally been the standard technique for tracheal intubation. However, videolaryngoscopes, which allow indirect visualisation of the glottis via a camera, have been increasingly adopted in clinical practice. Randomised trials across different clinical settings, including critically ill patients in intensive care units and patients undergoing surgery in the operating room, have shown that videolaryngoscopy improves glottic visualisation and increases first-attempt intubation success compared with direct laryngoscopy.[3 4] Consistent findings have been reported in meta-analyses across diverse clinical scenarios.[5] A recent large multicentre study conducted under real-world conditions further supported these findings, showing improved intubation conditions and reduced complications with the routine use of videolaryngoscopy.[6]

In paediatric patients, this question is particularly relevant. Anatomical and physiological characteristics, including a more anterior larynx, higher oxygen consumption and lower functional residual capacity, make airway management more challenging and reduce the margin of safety during tracheal intubation. As a result, maximising first-pass success is of critical importance in this population.[7]

Randomised trials in paediatric populations have reported conflicting results. Some studies in neonates and infants have shown that videolaryngoscopy increases first-attempt intubation success and reduces complications compared with direct laryngoscopy.[8 9] In contrast, other randomised studies in paediatric surgical patients have reported no improvement in first-attempt success or similar or less favourable performance of videolaryngoscopy in terms of intubation time or technical difficulty.[10–12] A recent systematic review and meta-analysis including 53 randomised controlled trials and 4887 paediatric patients found no statistically significant difference in first-attempt intubation success between videolaryngoscopy and direct laryngoscopy (risk ratio 1.03, 95% CI 0.99 to 1.07), despite improved glottic visualisation with videolaryngoscopy.[13] These findings highlight the need for large, pragmatic, multicentre randomised controlled trials in unselected paediatric surgical populations to inform routine clinical practice.

Given that millions of paediatric patients undergo surgery requiring tracheal intubation each year, even small improvements in first-attempt success could translate into a substantial reduction in adverse events at the population level. The VIDEOKIDS trial was designed to address this knowledge gap. This pragmatic, international, multicentre randomised controlled trial aims to compare videolaryngoscopy with direct laryngoscopy as the initial technique for tracheal intubation in paediatric patients undergoing surgery under general anaesthesia. We hypothesise that videolaryngoscopy will increase the frequency of successful intubation on the first attempt.

Study aims and objectives

Primary objective

The primary objective of this study is to determine whether videolaryngoscopy increases the frequency of first-attempt success compared with direct laryngoscopy in paediatric patients undergoing surgery under general anaesthesia.

Secondary objectives

The secondary objectives are to compare, between videolaryngoscopy and direct laryngoscopy, time to successful intubation, number of intubation attempts, laryngoscopic view assessed using the modified Cormack-Lehane classification, need for adjunct airway devices, intubation difficulty as assessed by the anaesthesiologist and the incidence of intubation-related complications.

Study design

The VIDEOKIDS trial is a prospective, international, multicentre, open-label, randomised, controlled superiority trial.

METHODS: PARTICIPANTS, INTERVENTIONS AND OUTCOMES

Study settings

The VIDEOKIDS trial will be conducted in approximately 20–25 hospitals across six countries: Spain, Portugal, Uruguay, Mexico, Colombia and Brazil.

Eligibility criteria

Inclusion criteria

- Paediatric patients aged 0–16 years.
- Undergoing elective or urgent surgery under general anaesthesia requiring tracheal intubation.
- Planned tracheal intubation with videolaryngoscopy or direct laryngoscopy as the initial technique.
- Written informed consent obtained from parents or legal guardians, in accordance with applicable regulations.

Exclusion criteria

- Known airway anatomical abnormalities or clinical conditions requiring a specific intubation technique (eg, fibreoptic intubation).
- Requirement for emergency tracheal intubation that does not allow adequate randomisation.
- Refusal of parents or legal guardians to participate in the study.

Assignment and intervention

Allocation

Eligible patients will be randomly assigned in a 1:1 ratio to undergo tracheal intubation using either

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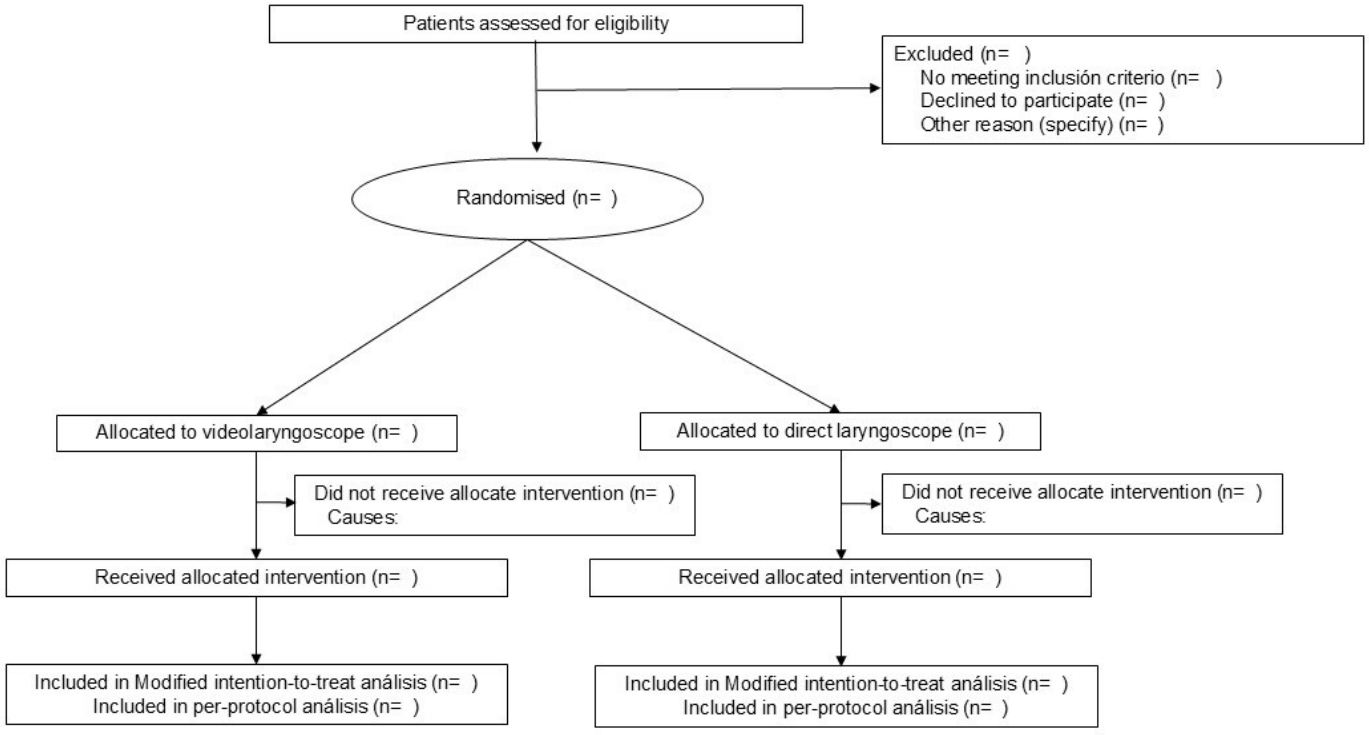

Figure 1 The Consolidated Standards of Reporting Trials (CONSORT)[15] diagram of the VIDEOKIDS trial.

videolaryngoscopy or direct laryngoscopy for the first attempt. Randomisation will be performed using a computer-generated sequence with permuted blocks of variable size, stratified and balanced by centre and age group (<28 days, 28 days to 1 year, and >1 year to 16 years). The assignment to each study group will be generated using a computerised randomisation sequence, placed in sequentially numbered opaque envelopes and distributed to the participating hospitals. The patient recruitment, randomization, and allocation process is presented in (figure 1).

Blinding

Blinding of the anaesthesiologist to the allocated intervention is not feasible due to the nature of the procedures. Patients will be under general anaesthesia and therefore unaware of group allocation. The anaesthesiologist will be informed of the allocated technique (videolaryngoscopy or direct laryngoscopy) prior to induction of anaesthesia.

Interventions

Before enrolment, participating anaesthesiologists at each centre will receive standardised information about the study protocol and training in the use of both videolaryngoscopy and direct laryngoscopy according to local practice.

Patients assigned to the videolaryngoscopy group will undergo tracheal intubation using a videolaryngoscope with a standard blade (Macintosh or Miller) for the first attempt, according to clinician preference and local practice. The specific device used will be recorded.

Patients assigned to the direct laryngoscopy group will undergo tracheal intubation using a conventional direct laryngoscope with a standard blade (Macintosh or Miller) for the first attempt, according to clinician preference and local practice.

In both groups, all other aspects of airway management will be at the discretion of the attending anaesthesiologist, including patient positioning, preoxygenation strategy, choice and dosing of hypnotic and neuromuscular blocking agents, endotracheal tube size and the use of adjunct airway devices such as a stylet or bougie.

Operators will be encouraged to use the assigned technique for the first attempt but may deviate if deemed necessary for patient safety. If the first intubation attempt is unsuccessful, subsequent airway management will be performed according to the clinician's judgement, without restrictions on the choice of device or technique. The type of device used during the first and final intubation attempts will be recorded.

OUTCOME MEASURES

Primary outcome measure

The primary outcome is successful tracheal intubation on the first attempt, defined as placement of an endotracheal tube in the trachea following a single insertion of the laryngoscope blade into the mouth, without its removal.

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Secondary outcome measures

- Number of laryngoscopy attempts.
- Number of attempts to place the endotracheal tube.
- Glottic view assessed using the modified Cormack-Lehane classification.
- Glottic view assessed using the percentage of glottic opening score.
- Incidence of 'easy intubation', defined as a modified Cormack-Lehane grade I or IIa view together with successful intubation on the first attempt.
- Duration of tracheal intubation, defined as the time from insertion of the laryngoscope blade into the mouth until passage of the endotracheal tube through the vocal cords.
- Need for adjunct airway devices for intubation, including bougie, stylet or other devices.
- Need to change the intubation device for tracheal intubation.
- Degree of difficulty of tracheal intubation as assessed by the anaesthesiologist (without difficulty, mild, moderate and severe difficulty).
- Reasons for failure of first-attempt intubation, including inadequate view of the larynx, inability to advance the endotracheal tube into the trachea, aborted attempt due to a change in patient condition (eg, hypoxaemia, bradycardia, bleeding or vomiting), technical failure of the device or other reasons.
- Complications during tracheal intubation and within 10 min after successful intubation, including oxygen desaturation <90%, oesophageal intubation, bradycardia, pulmonary aspiration, laryngospasm, bronchospasm, dental injury, airway injury, cardiac arrest and other airway-related adverse events.[14]

Participant timeline

The participant timeline is described in table 1.

Table 1 Participant timeline

Time point	Decision to perform TI	During TI	0–15 min after TI
Eligibility assessment	X		
Informed consent	X		
Enrolment	X		
Demographic data	X		
Patient characteristics	X		
Physical examination	X		
Interventions:			
Laryngoscope standard (Macintosh, Miller)		X	
Videolaryngoscope McGrath		X	
Another device		X	
Screening for contraindications	X	X	
Assessments:			
First-pass success rate		X	
Glottic view		X	
Need of adjuvant airway device		X	
Occurrence of complications		X	X
Difficulty of TI assessed by the anaesthesiologist			X

TI, tracheal intubation.

Recruitment

Trial investigators will screen and enrol consecutive eligible paediatric patients undergoing surgery under general anaesthesia at participating centres. The trial will be conducted in approximately 20–25 hospitals across six countries: Spain, Portugal, Uruguay, Mexico, Colombia and Brazil. Enrolment began in May 2026 and is expected to be completed in December 2027.

Data collection, management and analysis

Data collection and management

All outcome measurements will be recorded during and immediately after the intubation procedure by an independent and trained observer using a standardised case report form (CRF). Trained observers may include clinical personnel at each participating centre, such as anaesthesiologists or nurses.

Pseudonymised data will be collected and managed using REDCap (Research Electronic Data Capture), a secure, web-based software platform hosted at the Sanitary Research Institute of Santiago de Compostela (IDIS). REDCap provides an intuitive interface for validated data entry, audit trails for tracking data manipulation and export procedures, automated export functions to common statistical software and tools to support data integration and interoperability with external sources.

The study database will be protected by encryption, and individual user access will be granted to each participating centre through password-protected accounts. Each enrolled patient will be assigned a unique study identification number. Protocol deviations and adverse events will be recorded in the electronic CRF (eCRF). A clinical research assistant will ensure that all relevant data, protocol deviations and adverse events are accurately recorded in the database.

Access to data

Data safety, data quality and statistical analysis will be overseen by three designated investigators (TS-P, OV and MT), who will be responsible for identifying and addressing any issues that may arise during the study. Data will be collected and stored in accordance with Good Clinical Practice guidelines and applicable data protection regulations. Access to the data will be granted to participating study centres. Any issues arising during the study will be reported to these investigators. The variables collected are described in tables 2–5.

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Table 2 Baseline characteristics of the patients

Characteristic of patients at baseline	Overall (n=….)	Video laryngoscope (n=….)	Direct laryngoscope (n=…)
Age, median (IQR), years, months			
Distribution, no. (%)			
<28 days			
28 days to <1 year			
≥1 year to <16 years			
Female sex, no. (%)			
Weight, median (IQR), kg			
Height, median (IQR), cm			
ASA physical status, no. (%)*			
I			
II			
III			
IV			
V			
Surgical procedure, No. (%)			
Otorhinolaryngological surgery			
Adenoidectomy and/or tonsillectomy			
Orthopaedic surgery			
General surgery			
Cardiac-vascular surgery			
Neurosurgery			
Urological surgery			
Oral and maxillofacial surgery			
Thoracic surgery			
Plastic surgery			
Gynaecological surgery			
Transplant surgery			
Other (radiology, haemodynamic,…)			
Medications used, No. (%)			
Hypnotic agent, No. (%)			
Propofol			
Etomidate			
Ketamine			
Sevoflurane			
Isoflurane			
Midazolam			
Other			
Neuromuscular blockade, No. (%)			
Succinylcholine			
Rocuronium			
Cisatracurium			
Other			
No neuromuscular blockade used			
Neuromuscular blockade monitoring			
Data of procedure, No. (%)			
May–August 2026			

Continued

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Table 2 Continued

Characteristic of patients at baseline	Overall (n=….)	Video laryngoscope (n=….)	Direct laryngoscope (n=…)
September–December 2026			
January–April 2027			
May–August 2027			
September–December 2027			

*ASA Classification refers to the American Society of Anesthesiologists Physical Status Classification System, a scale used to assess and communicate a patient's preoperative health status. It ranges from ASA I (a healthy patient with no systemic disease) to ASA V (a moribund patient who is not expected to survive without the operation).

Statistical methods

Description of the patient groups at baseline and time period for analysis

Baseline characteristics of all enrolled patients will be described according to study group. Categorical variables will be presented as counts and percentages, and continuous variables as mean (SD) or median (IQR), as appropriate. Normality will be assessed using the Kolmogorov-Smirnov test with Lilliefors correction.

Primary analysis

The primary analysis will be an unadjusted comparison of successful first-attempt tracheal intubation between the videolaryngoscopy group and the direct laryngoscopy group, performed according to the intention-to-treat principle.

The primary outcome will be compared between groups using the χ^2 test. The treatment effect will be expressed as the absolute risk difference with corresponding 95% CIs. Relative risks and 95% CIs will also be reported.

Secondary analysis

Secondary outcomes

Secondary outcomes will be analysed according to the intention-to-treat principle, comparing patients assigned to the videolaryngoscopy group with those assigned to the direct laryngoscopy group. Continuous variables will be compared using the Wilcoxon rank-sum test, and categorical variables using the χ^2 test or Fisher's exact test, as appropriate. Treatment effects will be reported as between-group differences with corresponding 95% CIs.

Per-protocol analysis

A per-protocol analysis will be performed as a sensitivity analysis, including patients who underwent the first intubation attempt with the device assigned at randomisation and without major protocol deviations affecting the primary outcome

Effect modification (subgroup analyses)

We will investigate whether predetermined baseline variables influence the effect of the study group on the primary outcome. To assess this, we will use a logistic regression model focused on the primary outcome of first-attempt success. The independent variables in the model will consist of the study group assignment, the potential effect modifier of interest, and the interaction between these two factors. Significance will be assessed by the p value for the interaction term, with values under 0.10 indicating a possible interaction and values under 0.05 confirming an interaction. Subgroups from categorical variables will be shown as forest plots. Continuous variables will be analysed using cubic splines with 3 to 5 knots. If needed for data presentation, continuous variables will be dichotomised for inclusion in forest plots:

Prespecified subgroups that may modify the effect of study group on the primary outcome (table 6):

1. Age group (<28 days, 28 days to 1 year, >1 year to 16 years).
2. Weight (≤10 kg vs >10 kg).
3. Rank of the operator (resident, attending anaesthesiologist with ≤5 years of experience, attending anaesthesiologist with >5 years of experience).
4. Skill level of the anaesthesiologist performing the first intubation attempt.
   a. Number of previous intubations performed with videolaryngoscopy (>50, 20–50, <20).
   b. Number of previous intubations performed with direct laryngoscopy (>50, 20–50, <20).
   c. Number of previous intubations performed with any device (>50, 20–50, <20).
5. Indication for intubation (tonsil/adenoid surgery vs other).
6. Route to intubation (oral vs nasal).

Multivariable modelling to account for confounding

A prespecified adjusted analysis of the primary outcome will be performed using a mixed-effects logistic regression model, with successful intubation on the first attempt as the dependent variable. Study group (videolaryngoscopy vs direct laryngoscopy) will be included as a fixed effect, and study site will be included as a random effect to account for clustering by centre. Prespecified baseline covariates considered clinically relevant will be included as fixed effects, including age, weight, operator seniority and prior experience with videolaryngoscopy. Continuous covariates will not be categorised for analysis and will be modelled using appropriate functional forms when necessary. Continuous variables may be categorised

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Table 3 Characteristics of the operator and intubation procedure

Characteristic of intubation procedure	Overall (n=….)	Video laryngoscope (n=….)	Direct laryngoscope (n=…)
Device used as first intention intubation, No. (%)			
Direct laryngoscope			
Straight (Miller)			
Macintosh type			
Videolaryngoscope			
Straight (Miller)			
Macintosh type			
Rank of the first operator, No. (%)			
Resident			
Attending (<5 years' experience in paediatric tracheal intubation)			
Attending (≥5 years' experience in paediatric tracheal intubation)			
Need to change the first operator			
Experience with direct laryngoscope intubation, No. (%) (number of paediatric intubations)			
<20 intubations			
20–50 intubations			
>50 intubations			
Experience with videolaryngoscope intubation. No. (%) (number of paediatric intubations)			
<20 intubations			
20–50 intubations			
>50 intubations			
Type of intubation, No. (%)			
Elective			
Urgent			
Airway management, No. (%)			
Rapid sequence induction			
Apneic oxygenation			
Nasotracheal intubation			
Cuffed tracheal tube			
External laryngeal manipulation, No. (%)			
BURP maneuver*			
Sellick maneuver†			
OELM			
Other			
Position during intubation			
Supine ► Neutral ► Sniffing ► Shoulder roll			
Ramping			
Other			

Values are number (proportion).
*BURP manoeuvre is a technique used during intubation to improve visualisation of the vocal cords.
†Sellick manoeuvre, also known as cricoid pressure, involves applying firm pressure on the cricoid cartilage to occlude the oesophagus and prevent regurgitation of gastric contents during intubation.
BURP, Backward, Upward, Rightward Pressure; No, number; OELM, optimal external laryngeal manipulation.

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Table 4 Primary and secondary outcomes

Outcome	Video laryngoscope (n=….)	Direct laryngoscope (n=….)	Absolute risk difference (95% CI) or median difference
Primary outcome, No. (%)			
Successful intubation on the first attempt			
Modified intention to treat analysis			
Per-protocol analysis			
Secondary outcomes, No. (%)			
Successful intubation on the first attempt without desaturation <90%			
Laryngoscopy attempts			
1			
2			
≥3			
Tracheal intubation attempts (bougie or endotracheal tube)			
1			
2			
≥3			
Time of successful tracheal intubation, median (IQR), seconds			
Lowest oxygen saturation during airway management; median (IQR), %			
POGO score*			
76–100 (full view of the glottis)			
51–75 (partial view of glottis)			
26–50 (only half of vocal cord and arytenoid visible)			
1–25 (only lower fourth of vocal cord and arytenoid visible)			
0 (no glottic structure visible)			
Best modified Cormack-Lehane view†			
Grade I			
Grade IIa			
Grade IIb			
Grade III			
Grade IV			
Complete or partial view (I–IIa)			
Easy intubation‡			
Need of adjuvant airway devices for intubation			
Not			
Stylet			
Bougie			
Flexible-tip bougie			
Other			
Need to change the device for intubation			
Need to change the operator			
Degree of difficult intubation			
Not difficult			
Slight difficult			
Moderate difficult			
Severe difficult			
Reason for failure/abandoning first attempt			
Insufficient view			
Failure to advance tube			

Continued

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Table 4 Continued

Outcome	Video laryngoscope (n=….)	Direct laryngoscope (n=….)	Absolute risk difference (95% CI) or median difference
Need for extra device			
Need to change technique			
Need to change the operator			
Drop in oxygenation			
Other			

Values are number (proportion).
*POGO score, defined as the percentage (0%–100%) of the glottic opening visualised during laryngoscopy, where 0% indicates no visualisation of the glottis and 100% indicates full visualisation from the anterior commissure to the interarytenoid notch.
†Modified Cormack-Lehane grading system classifies laryngeal views during direct or video laryngoscopy. Grades I and IIa represent favourable views with good or partial visualisation of the glottis, while grades IIb, III or IV indicate progressively poorer views.
‡'Easy intubation', defined as a composite of tracheal intubation on the first attempt, easy laryngoscope (modified Cormack-Lehane grades of I or IIa) and no need for adjuvant airway devices.
No, number; POGO, Percentage of Glottic Opening.

for graphical presentation only. Effect estimates will be reported as adjusted ORs with corresponding 95% CIs.

Missing data and sensitivity analyses

Given that the primary outcome is assessed at the time of the procedure, we anticipate minimal missing data. Analyses of the primary outcome will be performed using available data. The per-protocol analysis will serve as a sensitivity analysis.

Sample size calculation

The trial is designed to compare the incidence of successful tracheal intubation on the first attempt between videolaryngoscopy and direct laryngoscopy in paediatric patients undergoing surgery under general anaesthesia.

Based on the most recent systematic review and meta-analysis of paediatric randomised trials comparing videolaryngoscopy with direct laryngoscopy, first-attempt success was reported in 38 randomised trials including 3846 patients.[13] The aggregated event rates were 84.9% (1637/1928) for direct laryngoscopy and 89.2% (1710/1918) for videolaryngoscopy. Although the meta-analysis did not demonstrate a statistically significant difference between techniques (RR 1.03, 95% CI 0.99 to 1.07), we used the observed direct laryngoscopy success rate of approximately 85% as the baseline rate for our sample size calculation and assumed a conservative absolute improvement of 3 percentage points with videolaryngoscopy, corresponding to an expected first-attempt

Table 5 Tracheal intubation (TI) complications

Complications	Video laryngoscope (n=….)	Direct laryngoscope (n=….)	Absolute risk difference (95% CI) or median difference
Any complication			
≥3 attempts of intubation			
Hypoxaemia (SpO2 <90%)			
Moderate hypoxaemia (SpO2 <80%)			
Severe hypoxaemia (SpO2 <70% or hypoxia-related bradycardia)			
Bradycardia			
Oesophageal intubation			
Pulmonary aspiration			
Laryngospasm with need for treatment			
Bronchospasm with need for treatment			
Accidental tracheal tube dislocation (after successful TI)			
Airway, oral, soft tissue or dental trauma			
Bleeding and secretions difficult vision			
Other			

Values are number (proportion).
SpO2, peripheral oxygen saturation.

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Table 6 Subgroup analyses of the primary outcome

Subgroup	Video laryngoscope (n = …)	Direct laryngoscope (n = …)	Absolute risk difference (RD) (95% CI) percentage points
Overall			
Age			
<28 days			
28 days to <1 year			
≥1 year to <16 years			
Sex			
Male			
Female			
Weight			
≤10 kg			
>10 kg			
Rank of the operator			
Attending ≥5 years			
Attending <5 years			
Resident			
Experience of tracheal intubation with any device			
<20 paediatric intubations			
20–50 pediatric intubations			
>50 paediatric intubations			
Experience of tracheal intubation with videolaryngoscopy			
<20 paediatric intubations			
20–50 pediatric intubations			
>50 paediatric intubations			
Experience of tracheal intubation with direct laryngoscopy			
<20 paediatric intubations			
20–50 pediatric intubations			
>50 paediatric intubations			
Surgery			
Elective			
Urgent			
Route of intubation			
Oral			
Nasal			
Indication for intubation			
Tonsil/adenoid surgery			
Other surgery			

RDs and 95% CIs will be calculated for the primary outcome (successful intubation on the first attempt) comparing videolaryngoscopy with direct laryngoscopy across prespecified subgroups.
RDs will be estimated using generalised linear mixed-effects models, including study site as a random effect to account for between-centre variability. Fixed effects will include study group (videolaryngoscopy vs direct laryngoscopy), the prespecified subgroup (effect modifier) and the interaction between study group and subgroup.
A positive RD will indicate a higher probability of successful intubation on the first attempt in the videolaryngoscopy group compared with the direct laryngoscopy group.

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success rate of approximately 88%. With a 1:1 allocation ratio, a two-sided alpha level of 0.05, and 90% power, 2725 patients per group are required to detect an absolute between-group difference of 3 percentage points.

A 3-percentage-point absolute difference was considered clinically relevant given the association between failed first-attempt intubation and airway-related complications in paediatric patients. Given that the primary outcome is assessed at the time of the procedure, we anticipate minimal missing data. Allowing for 3% missing data, the target sample size will be 5620 patients, including approximately 2810 patients in each group.

Monitoring

Data monitoring

Before study initiation, all anaesthesiologists at participating centres will receive standardised training on the study protocol and data collection procedures using the CRF. All study-related documents will be made available to investigators.

Investigators will be responsible for patient screening and enrolment. Data will be recorded in a web-based eCRF by trained study personnel. The eCRF will be provided and managed by the Research Methodology Unit of the Fundación Instituto de Investigación Sanitaria de Santiago (FIDIS), Spain.

Each participant will be assigned a unique study identification number. Access to identifiable data will be restricted to authorised study personnel in accordance with applicable data protection regulations. Data quality will be ensured through range checks, consistency checks, and periodic central monitoring of the database. Queries will be generated and resolved by site investigators.

The principal investigators (MT, PD, JF and OV) will hold regular meetings with investigators at participating centres to review recruitment, data quality, protocol adherence, and overall study progress.

No independent data monitoring committee is planned given the low-risk nature of the study and the use of routinely applied clinical interventions.

Harms

The study interventions are part of routine clinical practice. Patient safety will be overseen by the attending anaesthesiologist, who may modify or discontinue the assigned technique at any time if clinically indicated.

Adverse events related to airway management will be recorded in the eCRF. Serious adverse events (SAEs) will include events such as cardiac arrest, death, severe hypoxaemia requiring intervention, vocal cord injury, oesophageal intubation with complications or other life-threatening complications related to airway management.

All SAEs will be reported in accordance with the standard operating procedures of the Ethics Committee of Galicia (CEImG). The principal investigator will notify the Ethics Committee of any SAEs occurring during the study. Given that both techniques are routinely used in clinical practice, no additional safety monitoring procedures are planned.

Auditing

The Research Methodology Unit of the FIDIS will perform periodic central monitoring of the study data, including review of screening logs, completeness of data and consistency of the information recorded in the eCRF. No on-site auditing is planned given the low-risk nature of the study.

Limitations of the study

The main limitation of this study is the lack of blinding. Due to the nature of the interventions, blinding of the anaesthesiologist performing the intubation is not feasible.

ETHICS AND DISSEMINATION

Research ethics approval

This study will be conducted in accordance with the current version of the Declaration of Helsinki and Good Clinical Practice guidelines. The study protocol was approved by the Ethics Committee of Galicia (CEImG), Galicia, Spain (reference number 2026/168). This approval applies to all participating centres in Spain, and institutional approval has been obtained from all Spanish participating hospitals. Approval has also been obtained from the participating centres in Brazil. Local ethical and regulatory approvals for the participating centres in Portugal, Uruguay, Mexico and Colombia are currently being processed and are expected to be obtained during September 2026. Recruitment at each participating centre will commence only after the required local approvals have been obtained. The VIDEOKIDS trial has been registered at ClinicalTrials.gov (NCT07495436).

Consent or assent

Written informed consent will be obtained from the parents or legal guardians before inclusion in the study, in accordance with the requirements of the Ethics Committee of Galicia (CEImG) and local regulations at each participating site (see online supplemental file 1 for an example of the participant consent/assent form).

Assent will be obtained from children when appropriate according to age and level of understanding and in accordance with local regulations.

Participants may withdraw from the study at any time at the request of the parents, legal guardians or the patient when applicable. Data from participants who request full withdrawal will not be included in the analysis.

Patient and public involvement

Patients and the public were not involved in the development of the research question, study design, outcome measures or conduct of the study. The results of the study will be made available to participants on reasonable request.

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Confidentiality

All study data will be handled in accordance with applicable data protection regulations. Identifiable patient information will be accessible only to authorised investigators and study personnel. Each participant will be assigned a unique study identification number and all analyses will be performed on pseudonymised data. Study records will be retained at participating sites for a minimum of 15 years. The final study database will be anonymised and securely stored.

Protocol changes

Any protocol modifications will be documented and updated in the ClinicalTrials.gov registry in accordance with Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines.

Dissemination plan

The results of the trial will be submitted for publication in a peer-reviewed journal and presented at national and international scientific meetings.

Trial status

Recruitment began in May 2026, with staggered initiation across participating centres, and is expected to be completed in December 2027.

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