

# BMJ Open Effect of a 3D-printed reconstruction automated matching system for selecting the size of a left double-lumen tube: a study protocol for a prospective randomised controlled trial

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## ABSTRACT

**Introduction** Lung isolation is primarily accomplished using a double-lumen tube (DLT) or bronchial blocker. A precise and accurate size of the DLT is a prerequisite for ensuring its accurate placement. Three-dimensional (3D) reconstruction technology can be used to accurately reproduce tracheobronchial structures to improve the accuracy of DLT size selection. Therefore, we have developed automatic comparison software for 3D reconstruction based on CT data (3DRACS). In this study, we aimed to evaluate the efficiency of using 3DRACS to select the DLT size for endobronchial intubation in comparison with using the 'blind' DLT intubation method to determine the DLT size, which is based on height and sex.

**Methods and analysis** This is a prospective, single-centre, double-blind randomised controlled trial. In total, 200 patients scheduled for lung resection using a left DLT will be randomly allocated to the 3D group or the control group at a 1:1 ratio. A 3DRACS will be used for the 3D group to determine the size of the DLT, while in the case of the control group, the size of the DLT will be determined according to patient height and sex. The primary outcome is the success rate of placement of the left DLT without fiberoptic bronchoscopy (FOB). The secondary outcomes include the following: successful intubation time, degree of pulmonary atrophy, grade of airway injury, oxygenation during one-lung ventilation, postoperative sore throat and hoarseness, and number of times FOB is used.

**Ethics and dissemination** Ethical approval has been obtained from our local ethics committee (approval number: SCCHEC-02-2022-155). Written informed consent will be obtained from all participants before randomisation, providing them with clear instructions about the purpose of the study. The results will be disseminated through peer-reviewed publications and conferences.

**Trial registration number** NCT06258954.

## INTRODUCTION

Lung isolation techniques are frequently employed during surgical procedures for patients undergoing various intrathoracic procedures to provide one-lung ventilation

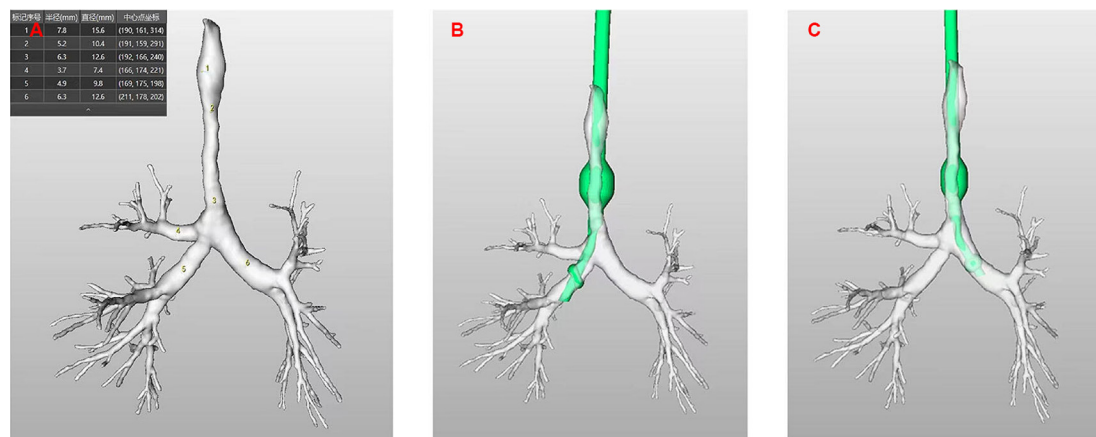
## STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This is a double-blinded, prospective randomised controlled trial.
- ⇒ The intention-to-treat analysis is the primary analysis and per-protocol analysis is applied as a sensitivity analysis.
- ⇒ A team of experts will re-evaluate the size of the double-lumen tube in order to protect the interests of the participants.
- ⇒ All images from the fiberoptic bronchoscopy assessment will be saved as a video and assessed by another endoscopist.
- ⇒ The single-centre design may limit its generalisability.

(OLV),<sup>1</sup> and these procedures are primarily performed with a double-lumen tube (DLT).<sup>2–3</sup> A study has reported that 40% of residents who do not have enough experience fail to accurately place DLTs.<sup>4</sup>

Currently, the criterion for selecting an appropriate DLT size is typically based on the patient's height and sex, but this criterion is not accurate enough. In some studies, the use of data from ultrasound or chest CT has demonstrated greater accuracy in determining the DLT size.<sup>5–7</sup> However, this approach has not been widely popularised due to the complexity of measurement and the increased workload.

Compared with CT devices, 3D printing systems can more accurately print tracheobronchial models, which can help to recommend more suitable DLT sizes. However, this process takes more time and is more expensive. To avoid the disadvantages mentioned earlier, we have developed an automatic software called the 3D reconstruction automatic comparison system (3DRACS), which helps to reconstruct tracheobronchial structures



**Figure 1** 3DRACS design. (A) Tracheobronchial 3D reconstruction using 3DRACS; (B) using 3DRACS, the size of the left DLT is selected. In a particular patient with a bronchial opening in the upper lobe of the right lung near the bulge, the insertion of a right DLT would make effective one-lung ventilation difficult; (C) the selection of a left DLT may be more suitable for one-lung ventilation. 3DRACS, automatic comparison software for 3D reconstruction; DLT, double-lumen tube.

and automatically measure the key data of tracheobronchial structures. These data are compared with 3D DLT images, and the 3DRACS software can recommend the size of a DLT (figure 1). We hypothesise that 3DRACS would improve the intubation success rate and accuracy in selecting DLTs and thereby reduce injuries.

## Objective

In this study, we aim to evaluate the efficiency of using 3DRACS to select the DLT size in terms of the success rate of left-DLT placement compared with that with use of the 'blind' DLT intubation method to select the DLT size, which is based on height and sex.

## METHODS AND ANALYSIS

### Study design

This study is a prospective, single-centre, double-blinded, randomised controlled trial conducted in accordance with the 2013 statement of the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT).<sup>8</sup> The study protocol will be approved by the Sichuan Cancer Hospital Ethics Committee (No. SCCHEC-02-2022-155). The study protocol is written in accordance with the SPIRIT statement. Written consent will be obtained from all participants before patient enrolment. The flow diagram and schedule are shown in figures 2 and 3.

### Inclusion criteria

Participants will be screened for inclusion if they meet the following criteria:

1. Aged 18–75 years.
2. American Society of Anesthesiologists Physical Status I–III.
3. Schedule for elective lung resection surgery under general anaesthesia with OLV using a left DLT.

### Exclusion criteria

Patients with any diagnosis or condition that may cause difficult incubation (spinal malformation, tracheal stenosis, tracheal tumour, bronchial tumour, distorted airway anatomy or tumours of the mouth or neck) are excluded from the study.

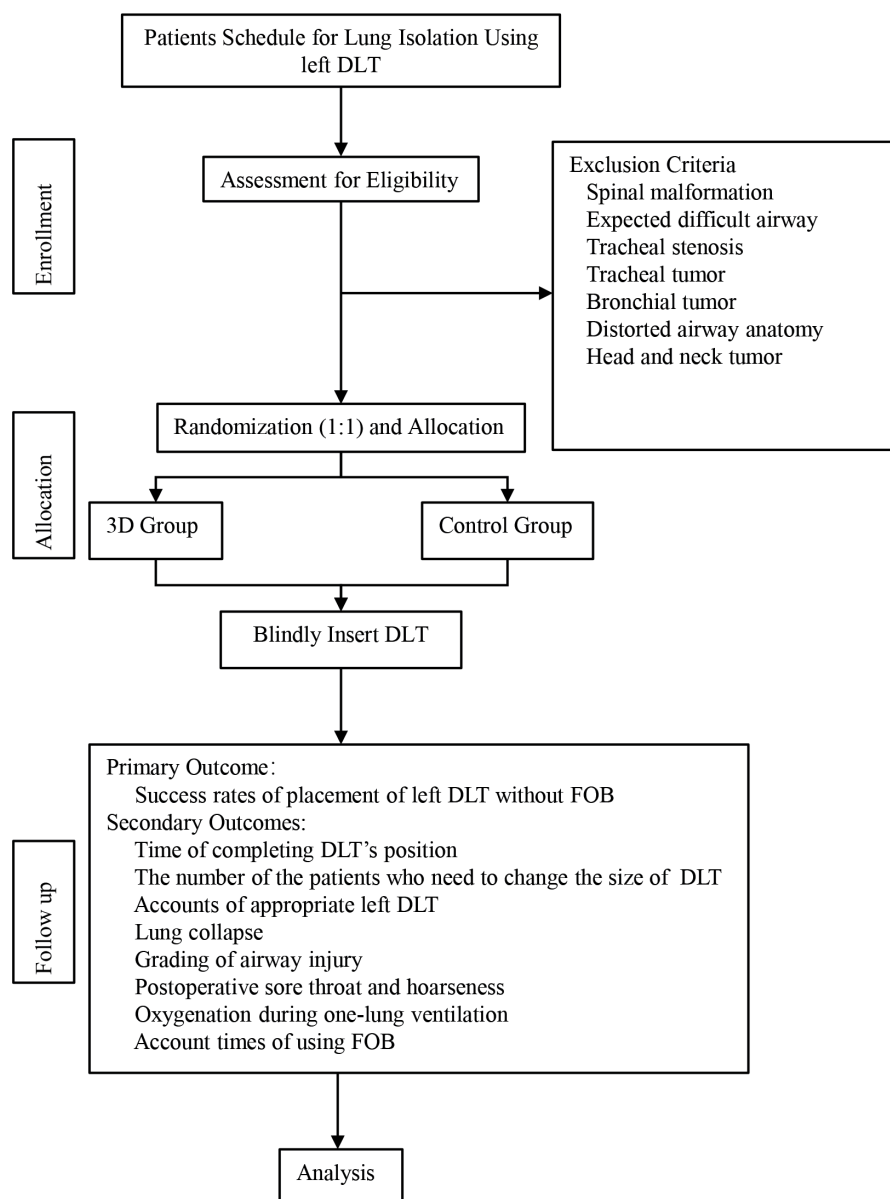
### Randomisation and blinding

A computer-generated randomisation list will be prepared by an independent researcher (YZ). Participants will be allocated randomly to the 3D group or the control group at a 1:1 ratio. Randomisation results will be concealed in sequentially numbered opaque envelopes by a researcher, YZ. Another researcher, HMW, will open the sealed envelope just before surgery and provide the designated DLT according to the group assignment. All participants and researchers involved in surgery, bronchoscopy assessment, follow-up, data management and analysis will be blinded to the group designation.

### Interventions

In the 3D group, the most suitable size of the left DLT will be determined by superimposing the tracheobronchial three-dimensional images with 3D images of the left DLT with 3DRACS. The distance between the vocal cord and carina will be calculated according to tracheobronchial three-dimensional images from the vocal cord slice to the carina slice. The largest-size left DLT will be fitted into this position once meeting the following criteria: (a) external diameter remaining within the internal tracheal lumen at the level of the narrowest part of the trachea with a difference  $\geq 2$  mm and (b) external dimensions not extending beyond the internal bronchial diameter at the level of 1 cm below the carina with a difference  $\geq 2$  mm.

In the control group, the size of the left DLT will be based on the patient's height and sex (ie, 32-Fr



**Figure 2** Study flow chart. DLT, double-lumen tube; FOB, fibreoptic bronchoscopy.

left DLT for height <1.50 m, 35-Fr left DLT for height 1.50–1.60 m and 37-Fr left DLT for height ≥1.60 m; men: 35-Fr left DLT for height <1.60 m, 37-Fr DLT for height 1.60–1.70 m, 39-Fr left DLT for height 1.70–1.80 m and 41-Fr DLT for height ≥1.80 m)<sup>9–11</sup> (online supplemental material 1).

Both the 3D group and the control group will undergo surgery as follows.

Positioning will be clinically confirmed by auscultating both lungs. If the position of the left DLT is inappropriate, the endotracheal and endobronchial cuffs will be deflated, the left DLT will be retracted 0.5 cm, and the position of the left DLT will be verified by auscultating both lungs again until the left DLT is at the optimal position.<sup>12</sup> A maximum of three placement attempts will be made to place the left DLT without fibreoptic bronchoscopy (FOB) guidance. If all three attempts fail, the left DLT will be

placed directly into the correct position under FOB guidance.<sup>13</sup> If the position of the left DLT under FOB guidance does not match and the intubation fails because of the improper size of the left DLT, we will need to switch to another left DLT.

FOB, which is considered the standard guiding modality for DLT placement, will be used to judge the final position of the left DLT in both groups intubated without FOB guidance (online supplemental material 2).<sup>4,9,14</sup> The results of the assessment will be recorded on a case report form (CRF). If the position of the left DLT is not accurate, it will be replaced under FOB guidance. All patients will be placed in a lateral position before the surgery, and FOB will be reused to ensure the correct positioning of the left DLT. However, this use of FOB will not be counted towards the number of times of FOB use or the final analysis.

	STUDY PERIOD						
	Enrolment	Allocation		Postallocation			
TIMEPOINTS	Preoperative	0d	DLT Intubation	Before surgery begins	End of surgery	1h after extubation	24h after extubation
ENROLMENT:							
Eligibility screen	X						
Inform consent	X						
Allocation		X					
INTERVENTIONS							
3D group			X				
Control group			X				
ASSESSMENTS							
Baseline variables	X						
Intraoperative data					X		
Success rates of placement of left DLT without FOB				X			
Time of completing DLT's position				X			
The number of the patients who need to change the size of DLT				X			
Accounts of appropriate left DLT				X			
Lung collapse					X		
Grading of airway injury						X	
Postoperative sore throat and hoarseness						X	X
Oxygenation during one-lung ventilation					X		
Times of using FOB					X		

**Figure 3** Schedule of enrolment, interventions and assessments. DLT, double-lumen tube; FOB, fiberoptic bronchoscopy.

### Anaesthesia management

All patients in the two groups will be placed in the supine position and monitored using invasive arterial blood pressure, electrocardiography and peripheral oxygen saturation in the operating room. Anaesthesia will be induced with 2 mg of midazolam, 1.5–2.5 mg/kg of propofol, 0.3–0.5 µg/kg of sufentanil and 0.2 mg/kg of cis-atracurium. All patients will be intubated with a left DLT by skilled investigators (HZ and LL) using one of the two intubation methods via laryngoscopy following current guidelines.<sup>9</sup>

Following tracheal intubation with a DLT, anaesthesia will be maintained with 0.1–0.2 µg/kg/min remifentanyl and sevoflurane at a 1–1.5 minimal alveolar concentration targeting a bispectral index value between 40 and 60. The values that will be applied during OLV are a tidal volume of 4–6 mL/kg (using the predicted body weight), a PEEP of 5–10 cmH<sub>2</sub>O and a respiratory rate adjusted to maintain an ETco<sub>2</sub> of 35–45 mm Hg. The train-of-four (TOF) count will be monitored every 5 min. Anaesthesia providers will be instructed to maintain a TOF count of 0 or 1 during the procedure. 30 min before the end of surgery, 8 mg of ondansetron will be administered to prevent postoperative nausea and vomiting. At the end of surgery, 0.02–0.04 mg/kg neostigmine will be used to

antagonise neuromuscular blockade with a TOF count of at least 3.

Multimodal analgesia, including intercostal nerve blockade, diazoxide and patient-controlled intravenous analgesia, will be administered to maintain a numerical pain rating scale score of <4. The intercostal nerves at T4–T9 will be blocked by the administration of 4 mL of 0.5% ropivacaine 4 mL into each intercostal space via video-assisted thoracoscopy performed by the surgeon at the end of the surgery. Diazoxide (5 mg) will be administered for analgesia 30 min before the end of surgery. Additionally, patient-controlled intravenous analgesia will be administered for postoperative analgesia.

### Follow-up

The patients will be assessed for hoarseness and sore throat in the PACU and ward after 1 and 24 hours of extubation, respectively. Sore throat will be assessed using the visual analogue scale (VAS). Other discomfort, including dry mouth and dysphagia, will be followed up at 24 hours after extubation. Cumulative opioid and additional analgesic consumption for 24 hours after extubation will also be recorded. The investigators assessing such outcomes will be blinded to the randomisation assignment.



## Outcomes

### Primary outcome

The primary outcome is the success rate of left-DLT placement without FOB. Success will be defined as not meeting any one of the following conditions: (a) a bronchial cuff herniation into the carina (more than 50% of the cuff) (too far out); (b) a bronchial cuff edge not visible at the entrance of the mainstem bronchus such that it would occlude a secondary bronchus (ie, placement too far inward); (c) presence of a double-lumen endotracheal tube in the right bronchus; or (d) inability to distinguish the tracheal/bronchial anatomy. The accurate position of placement confirmed using FOB is described in online supplemental material 2.

### Secondary outcomes

The secondary outcomes include the following:

1. The time required to reach the left DLT position. There are two different situations that we need to describe. The first situation is where the measured period starts when the cuff of the left DLT crosses the vocal cords and stops when the left DLT is successfully placed without FOB (attempts  $\leq 3$ ). A stopwatch is used for this purpose; the stopwatch is started when the cuff of the left DLT crosses the vocal cords and then stopped when the intubating anaesthesiologist considers the left DLT to be correctly positioned. The second situation is where the measured period starts when the cuff of the left DLT crosses the vocal cords and stops when the DLT is positioned successfully with FOB after three attempts all fail. Each attempt is defined as returning the bronchial lumen of the left DLT to the trachea and then attempting to reinsert it.
2. The number of patients who need to have the size of the left DLT changed: if the position of the left DLT under FOB guidance does not match and the intubation fails because of the improper size of the left DLT, we will need to switch to another left DLT.
3. Accounts of appropriate left DLTs: the objective criterion is injecting air into the cuff. When the pressure inside the left DLT reaches 25 mm Hg, the procedure will be stopped, and the DLT will be connected to the anaesthesia machine. The air leakage phenomenon will be adjusted when the peak pressure is lower than 30 cm H<sub>2</sub>O. An oversized left DLT is defined as one with which good pulmonary isolation can be achieved by injecting <1 mL of air into the bronchial cuff and <2 mL of air into the main tracheal cuff, while more than 3 or 6 mL of air injected into the two cuffs indicates an undersized left DLT.
4. Lung collapse: 10 and 20 min after pleurotomy, the degree of pulmonary atrophy will be assessed by a chest surgeon unaware of the grouping with an 11-point Likert scale, with 0 indicating no pulmonary atrophy at all and 10 indicating most perfect lung collapse.
5. The airway injury will be graded by a trained anaesthesiologist with more than 10 years of FOB experience who will assess tracheal and vocal cord-related injuries

from DLT intubation. Before the DLT is prepared for extubation, the FOB will be inserted into the bronchial lumen, and tracheal injury will be observed through the FOB as the DLT is extubated. All images from the FOB assessment will be saved as a video and later viewed by another endoscopist who will be blinded to the study protocol to assess vocal cord injury. The severity of tracheal injury will be defined as mild (redness, oedema, one to three speckled haemorrhagic lesions), moderate (over three mild lesions or one diffuse haemorrhagic lesion) or severe (more than two diffuse haemorrhagic lesions).<sup>15</sup> Lesions in vocal cords will be classified as oedema with inflamed mucosa, petechiae (small red spots on the mucosa) or haematoma (bleeding into the mucosa).<sup>15</sup>

6. Postoperative sore throat and hoarseness: defined as persistent resting pain in the throat region, where throat pain is assessed using the VAS score, that is, 0 for no pain and 10 for unbearable pain, while hoarseness is defined as a change in the quality of voice exhibited by the patient.<sup>15 16</sup>
7. Oxygenation during OLV: defined as the area under the curve of the SpO<sub>2</sub>/FiO<sub>2</sub> ratio during OLV. The SpO<sub>2</sub> and FiO<sub>2</sub> values will be automatically collected by the monitor at 30 s intervals, and any abnormal data due to equipment or human error will be replaced with the previous correct data.
8. Number of times FOB is used: defined as the number of times FOB guidance is used to place the left DLT correctly after three attempts all fail.

### Safety monitoring

Once the DLT size is chosen for the two groups, it will be assessed by an expert team of three anaesthesiologists with over 10 years of experience in DLT intubation. If the size of the DLT is considered grossly unsuitable, the appropriate size will then be chosen based on the expert team's opinion, in cases where the participant is defined as having failed intubation that is recorded in the CRF.

### Sample size

The sample size calculation is derived from Power Analysis and Sample Size (PASS, V.11; NCSS, Kaysville, Utah, USA) software. A total of 91 participants in each group is necessary to achieve 85% power and detect a difference between the group proportions of 0.2. The proportion in the 3D group is assumed to be 0.6 under the null hypothesis and 0.8 under the alternate hypothesis. The proportion in the control group is 0.6. The data will be analysed using a two-tailed Z test with unpooled variance. The significance level is set at 0.05. In the case of a 10% expected drop-out rate, we will enrol a total of 100 patients for each group.

### Statistical analysis

A biomedical statistician (FW) will perform the statistical analysis using R (R, V.4.0.3; Core Team, Vienna, Austria, 2020) software. Multiple imputations will be used

for missing data with percentages less than 10%.<sup>17</sup> After assessing the normality of continuous variables using the Kolmogorov-Smirnov test, normally distributed data will be presented as the mean (SD), and non-normally distributed data will be presented as the median (IQR). For categorical variables, the number and percentage (%) will be calculated. Baseline data between the two groups will be compared using Student's t-test, non-parametric tests,  $\chi^2$  tests or Fisher's exact test, according to the distribution of the data. The incidence of correct endobronchial intubation will be compared between the two groups using a  $\chi^2$  test or Fisher's exact test. Student's t-test or the Mann-Whitney U test will be used to detect differences in the time to successful intubation. For dichotomous outcomes, analysis will be performed using the  $\chi^2$  test and the logistic regression model. A two-tailed alpha level of 0.05 will be considered to indicate statistical significance. A full set analysis including all participants will be performed following the principle of intention-to-treat analysis. A per-protocol analysis will also be applied as a sensitivity analysis.

### Data management and quality control

Each participant will be given a unique record number, which is coupled with all electronic data, and all information about the patient will be recorded on a CRF according to the study protocol and then manually transferred from the CRF into an electronic data management system by two independent researchers, repeatedly, which will be validated to ensure correct entry. To protect privacy, the participants' personal information, such as the identification card number, telephone number, inpatient number and name, will be kept anonymous in the electronic data system. The electronic data will be kept in a password-protected folder accessible only to the researchers. After the trial is completed, the electronic data will not be allowed to be modified and will be sealed after the completion of the study. All electronic data will be deleted after 2 years, and paper-based data will be stored in the hospital for 10 years.

### Patient and public involvement

Patients and the public will not be involved in the design, conduct, reporting or dissemination of this research.

### Ethics and dissemination

The study protocol and informed consent form has been approved by the Ethics Committee of Sichuan Cancer Hospital (No. SCCHEC-02-2022-155). Written informed consent will be obtained before randomisation. The findings of the study will be submitted to a peer-reviewed journal and published. We also expect to share this information at academic conferences.

## DISCUSSION

This novelty of the project is explained by the fact that it is the first randomised, patient-blinded clinical trial

to investigate the effectiveness and safety of 3DRACS in selecting the left DLT size.

Lung cancer is the most prevalent cancer in China, and surgery is regarded as the primary treatment method.<sup>18 19</sup> The implementation of lung isolation techniques is an important prerequisite for the successful performance of minimally invasive pneumonectomy. Therefore, a suitable size and depth of the left DLT could improve the success rate of left DLT insertion,<sup>20 21</sup> which is one of the most commonly used techniques for performing lung isolation in clinical practice. We developed 3DRACS, which can automatically select the left DLT size based on CT data. This study hypothesises that the use of 3DRACS can improve the success rate of left DLT insertion and can better execute lung isolation than 'blind' DLT intubation methods.

Previous studies have also used bedside ultrasound for accurately selecting the size of the left DLT to measure the transverse diameter of the cricoid cartilage<sup>22 23</sup> or CT imaging for measuring the left main bronchus diameter to predict the left DLT size and cannula location.<sup>5</sup> Although these techniques have proven effective in predicting left DLT size based on height and weight, their 2D nature does not accurately reflect the actual 3D tracheobronchial tube.<sup>24</sup> Therefore, in this project, 3D data were used for more precise and accurate reflection of the actual tracheobronchial tube and may be able to predict the left DLT size more accurately.

The left DLT size is usually determined by the sex and height of the patient in clinical practice. However, this approach has certain disadvantages, as it does not work in some special populations (eg, Asian women, patients with large tumours, obesity and large-waisted patients, etc), and the use of CT or bedside ultrasound to measure tracheal and bronchial diameters requires specialist knowledge and equipment. In contrast, 3DRACS can automatically use CT data for 3D reconstruction to select the size of the left DLT, which translates into individual and accurate selection and is envisaged to reduce the time consumption and workload of physicians.

This study also has certain limitations. For example, it is a single-centre randomised controlled study, and the patients at our centre are mainly from Southwest China; therefore, the effectiveness and safety of this approach in other populations need to be clarified in further multicentre randomised controlled studies. Second, thoracic surgery is a major surgery performed at our hospital; therefore, anaesthetists have extensive experience in lung isolation, which may underestimate the effectiveness of 3DRACS; hence, its effectiveness when used by less experienced physicians in lung isolation, such as junior residents, needs to be confirmed in follow-up studies. Third, since in the control group, the position of the left DLT must be adjusted by auscultating both lungs, the anaesthesiologists performing the intubation will not be blinded, which might result in bias. However, these anaesthesiologists will not participate in the outcome assessments.

## Trial status

Recruitment will start on 1 April 2024, and this study is expected to be completed before 30 July 2024. Data collection and analysis will be completed within 1 month after trial completion. We expect to submit the research manuscript to a peer-reviewed journal before 30 December 2024.

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**Contributors** LL, YZ and HZ contributed to conception and design of the study. LL and YZ drafted the manuscript. FW provided the statistical analysis and interpretation of data. HZ, YZ, HY, HW and FF helped conduct the trial. WL and BD contributed to assess placement of DLT and vocal cord injury. YJ and HZ contributed to the review and critical revision of the manuscript. FY and YX contributed to data collection and follow-up. HZ sought funding. All authors have read and approved this final manuscript. Each author believes that their contribution is significant enough to warrant authorship and is willing to take public responsibility for their part of the work.

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