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Application of a new type of double-lumen endotracheal tube in preterm infants with respiratory distress syndrome: study protocol for a non-inferiority randomised controlled trial (NISA)

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ABSTRACT

Background Non-invasive ventilation combined with pulmonary surfactant (PS) therapy is recognised as a method for treating neonatal respiratory distress syndrome (NRDS). Among the administration, methods of PS, INtubation–SURfactant–Extubation (InSurE) and less invasive surfactant administration (LISA) have been widely discussed.

LISA technique prevents patients from exposure to invasive positive pressure ventilation (PPV), thus improving the long-term outcomes of the respiratory system, but it faces challenges in resource-limited areas due to complexity and cost. The InSurE technique remains prevalent due to its simplicity. The new dual-lumen tracheal tube (NDT) is designed with a 0.2 mm diameter pathway on the sidewall for continuous administration of PS under continuous PPV. The purpose of this study is to compare the safety and effectiveness of the NDT InSurE technique versus the LISA technique in non-invasive ventilation for premature infants with NRDS, and to explore the applicability of the NDT.

Methods and analysis This is a multicentre randomised controlled trial, planned to recruit 132 premature infants who meet the inclusion criteria from January 2024 to December 2024. They will be randomly assigned to the InSurE group using the NDT (experimental group) and the LISA group. The study will be conducted in six tertiary neonatal intensive care units in Yunnan province. The primary outcome is the rate of mechanical ventilation within 72 hours after birth. Secondary outcomes include the procedure data and major complications of NRDS, also include respiratory infections within 12 months of corrected age.

Discussion

We assume that the NDT is not worse than the LISA catheter. Based on the characteristics of the NDT, continuous PPV during drug administration, we designed this study to compare the InSurE technique using the NDT with the LISA technique. We aim to explore more benefits of the NDT and confirm wider clinical applicability. It will provide more options for doctors when using the InSurE technique.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ There is a lack of comparative research on the NDT INtubation–SURfactant–Extubation (InSurE) technique and less invasive surfactant administration, making this study innovative.
⇒ If the hypothesis is confirmed, clinicians will have an additional option when using pulmonary surfactant, and it may even replace endotracheal tube in InSurE technique.
⇒ The limited number of preterm infants planned for recruitment in the study may restrict stratified analyses based on gestational age, which could affect the broad applicability of the study results.
⇒ The study is limited to preterm infants with a gestational age of less than 32 weeks, which means that the results may not be applicable to preterm infants with a larger gestational age or other patient populations.

Ethics and dissemination This study complies with the Declaration of Helsinki and was approved by the medical ethics committee of Kunming Children's Hospital (approval number 2023-03-297-K01) and theoretical committee of Qujing Maternal and Child Health Hospital. At the end of the study, we will organise the data, complete the statistical analysis and present our research findings in the form of a paper.

There is lack of comparative research on the NDT InSurE technique and LISA, making this study innovative. If the hypothesis is confirmed, clinicians will have an additional option when using PS, and it may even replace endotracheal tube in InSurE technique. The limited number of preterm infants planned for recruitment in the study may restrict stratified analyses based on gestational age, which could affect the broad applicability of the study results. The study is limited to preterm infants with a gestational age of less than 32 weeks, which means that the results may not be applicable to preterm infants with a larger gestational age or other patient populations.

BACKGROUND

Neonatal respiratory distress syndrome (NRDS) is a critical condition that frequently confronts preterm infants immediately after birth, posing a significant threat to their survival. The incidence of respiratory distress syndrome (RDS) in preterm infants with a gestational age less than 28 weeks is close to 80%, of which about 50%–60% need to use pulmonary surfactant (PS).[1] Currently, the preferred treatment for NRDS is early continuous positive airway pressure ventilation combined with PS replacement therapy. The INtubation–SURfactant–Extubation (InSurE) technique has been widely adopted for PS application. However, the landscape of neonatal respiratory care is evolving with the advent of lung-protective ventilation strategies. Among these innovations is the less invasive surfactant administration (LISA) technique, which is gaining traction as an alternative to the InSurE approach.[2 3] LISA employs a fine catheter to deliver PS, enabling patients to maintain spontaneous breathing while continuing the established CPAP. The InSurE technique has been widely adopted for PS application.

The LISA technique has been confirmed to be an effective way to administer the pulmonary surfactant in treating NRDS. The most significant advantage of this technique is that it prevents patients from exposure to invasive positive pressure ventilation (PPV), thus improving the long-term outcomes of the respiratory system, possibly reducing the incidence of bronchopulmonary dysplasia (BPD). Still, there are some problems with LISA. The procedure of LISA per se is more complex than other techniques, such as the InSurE approach. When performing the LISA, the physicians sometimes need to use Magill forceps to hold a soft tube (usually a nasogastric tube) and insert it into the trachea while not discontinuing the non-invasive PPV (NPPV). This step can be challenging for some inexperienced doctors, leading to the interruption of NPPV or, even worse, the displacement of the nasogastric tube. As we know, the LISA procedure intends to maintain a continuous intermittent positive pressure ventilation (IPPV), which helps patients regain their functional residual capacity and prevent the alveoli from collapsing. Once the IPPV is discontinued, the efficacy of LISA will be significantly reduced. One alternative is using an LISA tube, a unique thin tube designed for the LISA procedure. It is thinner than the nasogastric tube, but much more rigid and easier to shape. Using an LISA tube is easier than a nasogastric tube for insertion, since it does not require the Magill forceps to hold it. Some types of LISA tubes are commercially available nowadays but costly. To sum up, the LISA technique is not conducive to promotion in some source-limited regions, especially in some remote provinces in China where medical technology is much more backward than in advanced places.

Increasing evidence suggests that LISA outperforms InSurE in several aspects, including its non-invasive nature, a reduction in the incidence of BPD and shorter hospital stays. Despite these advantages, the InSurE method remains widely used in many neonatal intensive care units (NICUs) worldwide due to its accessibility and the simplicity of the required medical devices. Furthermore, while LISA has demonstrated notable benefits, it is not significantly superior to InSurE in every case. Consequently, InSurE remains a reasonable alternative when LISA is unavailable.

Concerning the InSurE technique, the presence of some problematic issues can not be avoided. The biggest one is the administration of the PS and PPV share one inlet. This means the medication given via the endotracheal tube (ETT) will narrow the respiratory tract and impede ventilation.

In terms of hydromechanics, we know that the airway resistance is inversely proportional to the fourth power of the airway radius, which means minor obstruction of the ETT can generate considerable resistance and such a high resistance will significantly reduce the gas exchange leading to hypoventilation and life-threatening hypoxia.

Given the above concern, we invented a new dual-lumen tracheal tube (NDT) for the InSurE procedure. In this NDT, we use a thin tube (inner diameter 0.2 mm) integrated into the NDT's inner layer, and the outlet is located on the Murphy eye of the NDT (figure 1).[4] Such a clever design can bypass the central tract of the NDT and administer the PS at the distal site of the NDT, thus preventing the respiratory tract from being obstructed by the drugs.

To explore the potential application of the NDT and further confirm the broad applicability of this design, we have a hypothesis that the difference between using the NDT (experimental group) and the LISA technique delivering the PS is less than 10%. So, we plan to conduct a non-inferiority randomised controlled trial (RCT) to compare the safety and effectiveness between the InSurE technique using the NDT and the LISA tube technique in non-invasive ventilation for premature infants with RDS.

METHODS AND DESIGN

Aim

To compare the safety and effectiveness of the InSurE technology using the NDT and the LISA tube technology in non-invasive ventilation for premature infants with RDS.

Study design

This will be a multicentre prospective randomised controlled trail conducted in six tertiary NICUs in Yunnan province, China, from January 2024 to December 2024. The schedule of trial enrolment, interventions and assessments is presented in online supplemental file 2 (Standard Protocol Items: Recommendations for Interventional Trials checklist). The study will be followed by preset protocol shown in figure 2.

The NDT used in the study was patented in November 2019, with patent number: CN 209645598 U. It is manufactured by Henan Tuoren Medical Instrument Group

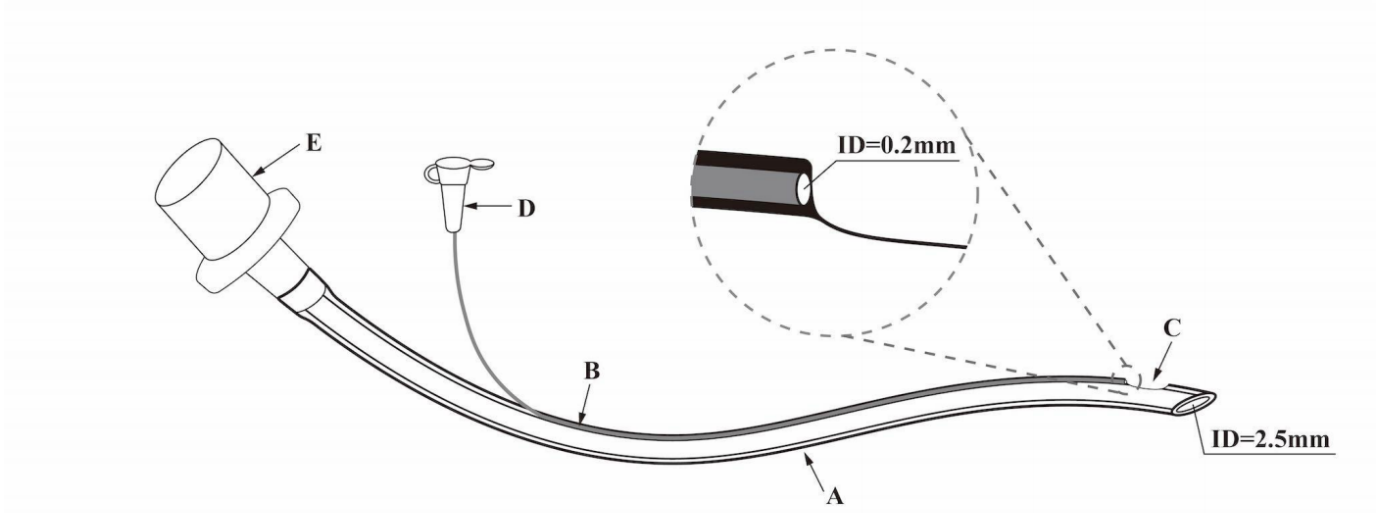

Figure 1 The new double-lumen tracheal tube diagram (take model 1 as an example) ID: Inner diameter. (A) The dominant tube whose diameter is chosen according to the weight of the newborn (model 1: ID 2.5 mm: model 2: ID 3.0 mm: model 3: ID 3.5 mm: model 4: ID 4.0 mm). (B) The drug delivery tube located inside the wall of the dominant tube with an ID of 0.2 mm. (C) The Murphy eye in direct communication with the distal end of the drug delivery tube. (D) The plastic cap for closing the drug injection port. (E) The tube connector.

under registration certificate number: Yu Xie Zhu Zhun 20172660345.

The LISA tube used in the study was manufactured by Wuxi Jiulong Medical Instrument. The registration certificate number is Su Xie Zhu Zhun 20192080040.

Inclusion criteria

Newborns meeting all of the following criteria will be considered for inclusion in the study:

1. Premature newborns born at a gestational age of less than 32 weeks.
2. Transferred to our NICU within 6 hours after birth and given non-invasive respiratory support with fractional inspired oxygen (FiO_2)>30% to maintain pulse oxygen saturation (SpO_2) between 90% and 95%.
3. Diagnosed with NRDS based on clinical presentation and chest imaging features.
4. Obtained written informed consent from parents (online supplemental material 1). (Recruiters will explain the content of the study in detail to the subject's guardian, and the guardian will sign a written informed consent based on understanding the content of the study.)

Exclusion criteria

If patients experiences any of the following conditions, they will be excluded from the study:

1. Severe congenital malformations, known complex congenital heart disease, or congenital pulmonary developmental abnormalities.
2. Chromosomal abnormalities or inherited metabolic disorders.
3. Neuromuscular diseases that affect respiratory function.
4. Grade 3 or 4 intraventricular haemorrhage (IVH) occurred within 24 hours after admission.
5. Receiving mechanical ventilation in the delivery room or immediately requiring mechanical ventilation support based on clinical judgement.
6. Exogenous surfactant were applied before enrolment.
7. Transferred out of the NICU before randomisation.
8. Surgical treatment is required.

Randomisation

The computer will randomly generate a randomised sequence of 132 numbers (with an odd–even ratio of 1:1) and place it in a sealed opaque envelope. The odd-numbered and even-numbered infants will be assigned to the InSurE group and the LISA group, respectively. Twins or multiple births will be randomly assigned to each group, which means they will be randomly assigned according to birth order. Each eligible patient will be randomly assigned to each group within 30 min by an independent person (a doctor from Kunming Children's Hospital who did not participate in this study).

Blinding: due to the significant differences in appearance and procedure between the two groups of interventions, blinding of clinicians and nursing staff is impossible, and blinding of patients is not meaningful. However, the generation and allocation of random numbers are done by individuals who do not participate in the study, and the researchers responsible for data analysis and outcome evaluation are also blinded.

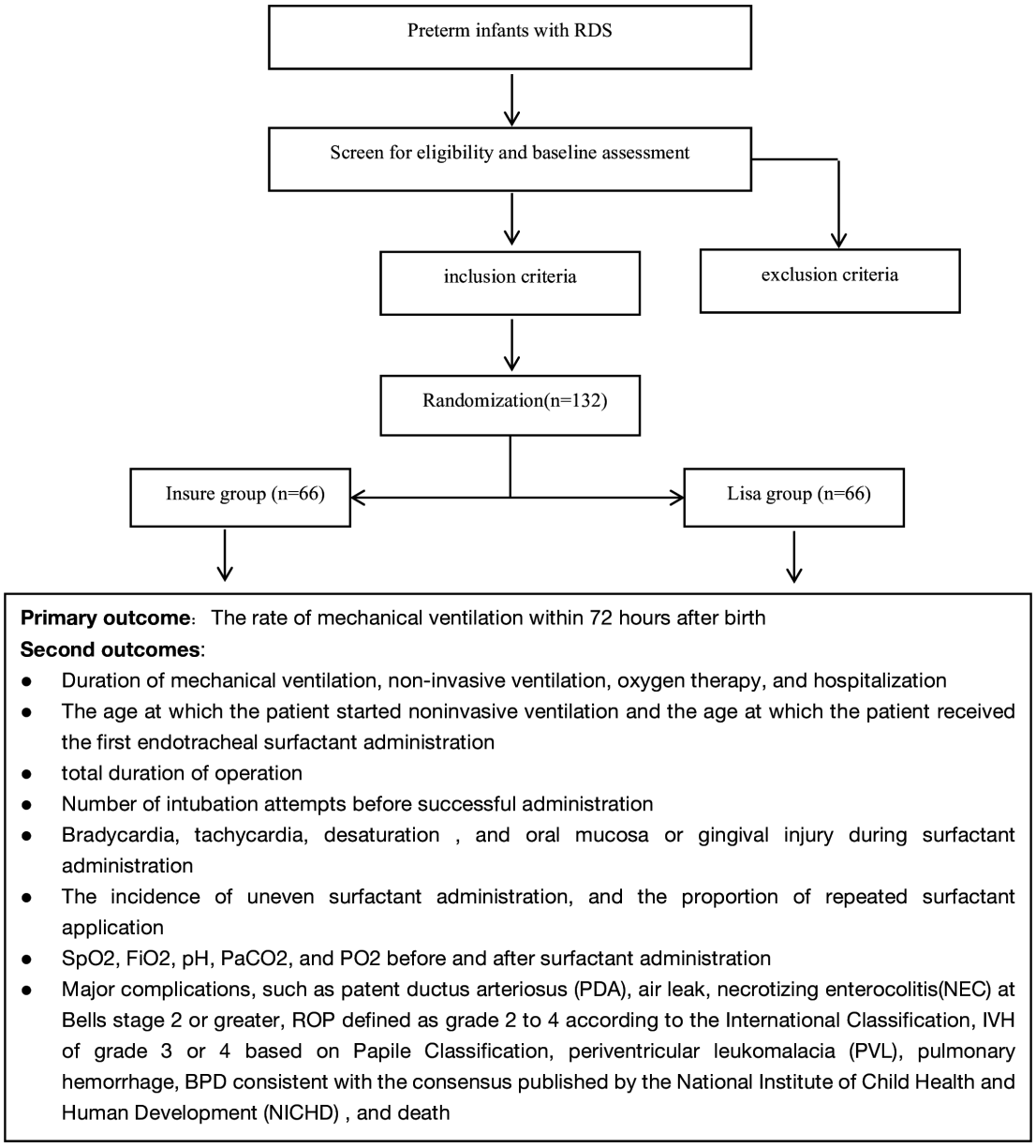

Figure 2 Flow diagram. BPD, bronchopulmonary dysplasia; FiO_2, fractional inspired oxygen; IVH, intraventricular haemorrhage; $PaCO_2$, partial pressure of carbon dioxide; PO_2, partial pressure of oxygen; RDS, respiratory distress syndrome; ROP, retinopathy of prematurity; SpO_2, pulse oxygen saturation.

Intervention

Surfactant administration procedure

When FiO_2 is adjusted above 30% to maintain target saturation, the InSurE or LISA procedure will be initiated for intratracheal surfactant therapy.[5]

Newborns assigned to the LISA group will receive surfactant administration through the LISA tube. Under direct laryngoscope guidance, a thin tube will be placed into the premature infant's trachea with or without Magill forceps.[6 7] The proximal interface of the LISA tube will be connected to a syringe, and surfactant will be administered at a slow rate. The newborns will remain non-invasive ventilation throughout. The thin tube will be removed immediately after the administration.

The procedure for surfactant administration via the InSurE technique is as follows. Non-invasive respiratory support will be suspended, followed by endotracheal intubation under direct laryngoscopy and anchored the NDT. The plastic cap of the NDT will be opened, and the surfactant will be slowly dripped in.[4] PPV will be maintained during the administration. The patient will be extubated and reintroduced to non-invasive respiratory support promptly as soon as the administration is completed.

To facilitate drug administration, the proximal end of the new catheter drug delivery tube extends outside the main wall, and the tip injection port is closed with a plastic cap. There is no difference of tracheal intubation operation between the NDT and the conventional tube.

The diameter of the tracheal tube is selected according to the weight of the newborn.

For both LISA and NDT, the depth of the tube insertion is as required in the section of tracheal Intubation in Neonatal Resuscitation.[8] Sedation or premedication was not used during either the InSurE or the LISA procedures

If the infant has a poor response to the first surfactant treatment or shows worsening of the condition, after initial exclusion of causes such as pneumothorax,[9 10] a second dose of surfactant will be considered using the same procedure. The timing of the second dose is determined by the clinician based on the baby's condition. Intratracheal surfactant administration can only be administered up to two times.

In China, two brands of PS are available. One is Curosurf, manufactured in Italy, and the other is a bovine lung surfactant manufactured in China. This study does not specify which type of PS should be used.

Criteria for non-invasive ventilation withdrawal

If the infant maintains the following conditions for 24 hours,[9] non-invasive ventilation will be considered for withdrawal: mean airway pressure (MAP) or positive end-expiratory pressure (PEEP) ≤3–5 cmH2O, FiO_2<25%, absence of apnoea or bradycardia requiring stimulation; acceptable SpO_2 (between 90% and 94%), normal respiratory rate, stable circulation.

Criteria for failure of the non-invasive ventilation protocol and subsequent acceptance of the mechanical ventilation programme

If any of the following conditions are met within 72 hours of birth, the patient's non-invasive ventilation treatment is considered to have failed and mechanical ventilation support is required immediately[11 12]: (1) Severe respiratory acidosis (arterial carbon dioxide tension ($PaCO_2$)>60 mm Hg, pH<7.2) confirmed by two arterial blood gas samples taken with an interval of more than half an hour. (2) Frequent apnoea (>3 times/hour), ineffective with pharmacological or non-invasive ventilation intervention. Pharmacological treatment of apnoea, in this study, we designed to start caffeine within 12 hours after birth. (3) Persistent hypoxemia (PaO_2<50 mm Hg or SpO_2<85% when FiO_2 is adjusted above 0.5). (4) Need for tracheal intubation for respiratory and cardiac arrest resuscitation and any type of neonatal pulmonary haemorrhage. (5) Other clinical emergencies.

End point of the study

If the patient meets one of the following conditions, the study will end: (1) the guardian decides to withdraw, (2) death, (3) reaching the corrected gestational age of 36 weeks or (4) discharge on medical advice, whichever comes first. After discharge, follow-up procedures will be carried out, until the corrected age reaches 12 months. Physicians will conduct a follow-up call to the parents every 4 months to inquire about the baby's condition after discharge from the hospital.

Primary outcome

The rate of mechanical ventilation within 72 hours after birth will be defined as the primary outcome.

Second outcomes

The following indicators are planned to be categorised as secondary outcomes:

1. Duration of mechanical ventilation, non-invasive ventilation, oxygen therapy and hospitalisation.
2. The age at which the patient started non-invasive ventilation and the age at which the patient received the first endotracheal surfactant administration, specified to the minute.
3. Total duration of the procedure (from the start of intubation to the end of drug injection).
4. Number of intubation attempts before successful administration. An attempt will be considered to have been generated when the laryngoscope is delivered into the neonate's mouth, regardless of whether a catheter is inserted, and the attempt will be judged to have been completed when both the laryngoscope and the catheter are removed from the mouth.[13]
5. Bradycardia (heart rate (HR)<100 beats/min), tachycardia (HR>200 beats/min), desaturation (SpO_2≤80%) and oral mucosa or gingival injury during surfactant administration.[14]
6. The incidence of uneven surfactant administration and the proportion of repeated surfactant application. Moreover, radiographs of the chest before and 4–6 hours after surfactant administration were compared, and cases with inconsistent improvement of bilateral lung lesions will be judged to be unevenly administered.
7. SpO_2, FiO_2, pH, $PaCO_2$ and partial pressure of oxygen before and after surfactant administration (blood gas analysis should be completed within 4 hours after administration). For infants who received multiple intratracheal surfactant administrations, data are reported for the first procedure only.
8. Major complications, such as patent ductus arteriosus, requiring medical or surgical treatment, pneumothorax, necrotising enterocolitis at Bells stage 2 or greater[15 16] retinopathy of prematurity defined as grade 2–4 according to the International Classification,[17] IVH of grade 3 or 4 based on Papile classification,[18] periventricular leukomalacia, pulmonary haemorrhage, BPD consistent with the consensus published by the National Institute of Child Health and Human Development[19 20] and death.
9. The subjects were followed up for 1 year (corrected age), including the number of upper or/and lower respiratory tract infections, the number of hospitalizations (any cause and for respiratory illness), the length of hospitalisation and the number of episodes of wheezing.

Other data: other infant information collected includes gestational age, birth weight, gender, delivery method, Apgar scores at 1 and 5 min, maternal pregnancy and

Timeline of the study and clinical data collection

TIMEPOINT	Study Period				
	Enrollment	Allocation	Post-allocation		
			Surfactant administration	72 hours after birth	end-point
Enrolment:					
Eligibility screen	×				
Informed consent	×				
Allocation		×			
Intervention					
InSurE			×	×	×
LISA			×	×	×
Assessments					
Primary outcomes					
The rate of mechanical ventilation within 72 hours after birth				×	
Second outcomes			×	×	×
Duration of mechanical ventilation, non-invasive ventilation, oxygen therapy, and hospitalization					
The age at which the patient started noninvasive ventilation and received the first endotracheal surfactant administration, Total duration of operation					
Number of intubation attempts before successful administration					
Bradycardia, tachycardia, desaturation , and oral mucosa or gingival injury during surfactant administration					
The incidence of uneven surfactant administration, and the proportion of repeated surfactant application					
SpO2, FiO2, pH, PaCO2, and PO2 before and after surfactant administration					
Major complications, such as patent ductus arteriosus (PDA) , air leak, necrotizing enterocolitis(NEC) at Bells stage 2 or greater, ROP, IVH, PVL) pulmonary hemorrhage, BPD , and death					

Figure 3 Follow-up schedule. BPD, bronchopulmonary dysplasia; FiO_2, fractional inspired oxygen; IVH, intraventricular haemorrhage; $PaCO_2$, partial pressure of carbon dioxide; PO_2, partial pressure of oxygen; PVL, periventricular leukomalacia; ROP, retinopathy of prematurity; SpO_2, pulse oxygen saturation.

delivery history, physical condition, family situation and prenatal steroid use.

Data collection

All data will be obtained from the electronic medical record systems of each hospital. Participating doctors will be responsible for completing the written case report forms (CRF) (online supplemental material 2). A dedicated coordinator will be responsible for entering the data from the CRF into the computer and monitoring the progress of the study. The data will be collected according to the following schedule (figure 3).

Sample size calculation

The sample size calculation for this study will be based on the rate of mechanical ventilation within 72 hours after birth. According to previous data,[4] the rate of mechanical ventilation for newborns with a gestational age less than 32 weeks within 3 days of birth is 30%. Assuming that the application of the NDT will reduce the risk by 20%, the non-inferiority margin is <−0.1, using PASS software (V.15.0) for one-sided testing, α is 0.025, β is 0.8, estimating a sample size of 59 per group. After considering various factors, such as missed diagnosis, incomplete data and early withdrawal, we ultimately decided to recruit at least 66 newborns per group.

Patient and public involvement

No patient involved.

Statistical methods

All data will be processed by SPSS 27 software. The difference will be considered statistically significant when the p value is less than 0.05. For continuous variables that conform to normal distribution and are represented as mean±SD, the independent samples t-test will be applied for comparison between groups. For continuous variables with skewed distribution and median (IQR), Mann-Whitney U test will be used for statistical analysis. For categorical variables represented by numbers (%), χ^2 test or Fisher's exact test will be selected. Logistic regression analysis will be used to explore the risk factors associated with failure of surfactant administration strategies, if necessary. This study will use the principle of intention to treat for data analysis. For missing data, we will use multiple imputation method for processing. For outliers, we will use box plot method for identification and conduct sensitivity analysis. For multiple comparisons, we will use Bonferroni method for correction. The lower bound of the 95% CI is preset to be −10%. If the final non-inferiority test result 95% CI is greater than −10%, then the NDT technique is non-inferior to the Lisa technique.

Data safety monitoring board

The board will have the following members:

Dr Kun Liang (KL1) , Professor of Neonatology, First Affiliated Hospital of Kunming Medical University.

Dr Yu He, Professor of Neonatology, Children's Hospital of Chongqing Medical University.

Dr Kai Liu (KL2) , Professor of Neonatology, Kunming Children's Hospital.

DISCUSSION

Pulmonary surfactant replacement therapy provides more survival opportunities for premature infants with NRDS. The InSurE and LISA techniques are currently the most widely used methods of administration. There have been many studies comparing the two methods. Some studies have confirmed that administration under spontaneous breathing is more conducive to uniform intrapulmonary surfactant distribution and improved pulmonary compliance than administration under PPV.[6] And there are also data suggesting that the application of the LISA technique can effectively avoid the use of mechanical ventilation during the first 72 hours after birth, while reducing mortality.[21 22] Nevertheless, there is no evidence to confirm that the administration of surfactant through a fine catheter has an overwhelming advantage.[4] According to an online questionnaire from 37 European countries, 69%, 41% and 34% of newborns experienced adverse effects of intratracheal surfactant reflux, bradycardia and hypoxia after receiving the LISA technique, respectively.[23] Data from India[7] and Poland[24] also showed no significant differences in the rate of endotracheal intubation within 72 hours after birth, duration of ventilation or incidence of BPD between the fine catheter and InSurE groups. The inconsistency of these research results indicates that more research is needed on the administration method of PS.

In the NDT, we designed a very thin channel that opens into the Murphy eye. The distal end of the new catheterised drug delivery tube does not go directly into the trachea, but is first connected to the trachea catheter through Murphy eye and then indirectly to the trachea. Moreover, since the drug delivery tube is located within the wall of the dominant tube, there is no thickening of the catheter due to this additional setting, let alone adding extra burden to the neonatal trachea as a result. The new catheter is designed with a unique administration route. After successful intubation, PPV can be continued until the end of administration without interrupting PPV in the middle. This is the advantage of the new catheter over the traditional ETT.

Nevertheless, these theoretical benefits must be supported by real-world data. Multiple comparisons help promote individualised treatment and technological advances.[25 26] Currently, comparisons of various endotracheal surfactant administration techniques in different populations have sprung up, but no consensus has been reached on the best technique. However, the ultimate goal of the various comparisons is not to determine the superiority or inferiority of the technologies, but rather to improve the overall understanding of each technology, to explore its potential benefits or risks and to analyse its advantageous and disadvantageous groups, which will promote personalised treatment for patients and facilitate the development of new technologies.

Furthermore, with preliminary data on safety and efficacy, there are still a number of gaps to be filled regarding the potential of the new tracheal catheter for neonates using non-invasive ventilation, and further confirmation of the clinical applicability of the new double-lumen tracheal catheter has become imperative. According to the previous data, the clinical applicability of the new double-lumen tracheal catheter can be reflected not only in the advantaged population but also in other populations, including newborns who receive the InSurE technique. Therefore, this particular RCT is planned to conduct an in-depth comparison between the InSurE technique by using the new tracheal tube and the LISA technique, and to further explore the potential benefits of double-lumen tracheal tube. If this is the case, this study will further confirm the widespread applicability of the new double-lumen tracheal intubation, suggesting that it may have the potential to completely replace traditional tracheal intubation when using the InSurE technique.

In conclusion, this will be an RCT comparing the safety and efficacy between the InSurE technique using the new tube and the LISA technique in preterm neonates. This trial aim to further explore the potential of the NDT,

which will provide a stronger basis for further multicentre RCTs with large sample sizes.

Ethics and dissemination

This study complies with the Declaration of Helsinki, and was approved by the medical ethics committee of Kunming Children's Hospital (approval number 2023-03-297-K01) and Theoretical Committee of Qujing Maternal and Child Health Hospital. The other four participating hospitals have agreed to use the ethics approval from the primary sponsor, Kunming Children's Hospital. Recruiters will explain the content of the study in detail to the subject's guardian, and the guardian will sign a written informed consent based on understanding the content of the study. All infants who meet the eligibility criteria must obtain consent from their parents or authorised guardians and sign an informed consent form (online supplemental material 2) before they can be randomised into groups. Trial investigators will allow monitoring, auditing and supervision related to the trial, by providing direct access to data sources and documents. The results of this study will be published in a peer-reviewed public journal. The trial will be conducted in accordance with good clinical practice and current regulatory guidance. At the end of the study, we will organise the data, complete the statistical analysis and present our research findings in the form of a paper.

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Contributors JG drafted the initial manuscript. JG obtained funding. YS and XD participated in the study design and recruited other centres to participate in the trial. CL designed the new double-lumen tracheal tube and participated in the revision of the protocol. JG, HX, PN, HY, DL, WY and JY will collect data. YS and JG recruited members of the data safety and monitoring committee, and YS approved the final version of the manuscript. All authors of the NISA research group read and approved the final draft and agreed to participate in the study. JG is the guarantor.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained from parent(s)/guardian(s).

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