

## **INFORMED CONSENT FORM**

**TITLE:** Effect of Mechanical Ventilation on Lung Development of Alveolar Stage

**PROTOCOL ID:** XH-21-12

**SPONSOR:** Xinhua Hospital, Shanghai Jiao Tong University School of Medicine

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## **Statement**

This is a clinical study approved by Xinhua Hospital Ethics Committee Affiliated to Shanghai Jiao Tong University School of Medicine. This form gives you important information about the study with description of research background, process and method, and please take time to review this information carefully.

Taking part in this study is completely voluntary. You do not have to participate if you do not want to, and you will not lose any benefits to which you are otherwise entitled. If you decide to take part in this study, you will be asked to sign this form.

## **Research background**

Human lung development begins in the early stage of intrauterine pregnancy, approximately 4-7 post-conception weeks (pcw), and lasts until 3 years after birth. It can be divided into five morphological stages, namely embryonic stage, pseudoglandular stage, canalicular stage, saccular stage and alveolar stage. Alveolar stage is the process of alveolar formation during which distal saccules divide into alveoli and fuse into capillary until completely surround it, contributing to the rapid increase of gas exchange surface. Alveolar stage spans from 36 pcw to 3 years of age, and thus could be influenced by external factors.

Mechanical ventilation (MV) is not only an important rescue method for critically ill children with respiratory distress, but also an indispensable respiratory support method for young children during pediatric surgeries. Different from spontaneous breathing which creates negative pressure in chest to bring in air, ventilators expand alveoli by pushing gas into lung with positive pressure. Therefore, no matter how ventilator nowadays has been optimized to provide breathing movement close to natural breathing, it still acts against physiological characteristics and has been reported to cause ventilator-induced lung injury when giving respiratory support to both pediatric and adult patients in intensive care unit. However, for children under the age of 3 with healthy pulmonary system, whether and how MV affects the alveolar stage of lung development has not been clearly elucidated.

Retinoblastoma (Rb) is a rare form of cancer that rapidly develops from the immature cells of a retina, the light-detecting tissue of the eye. It is the most common malignant cancer of the eye in children, and it is almost exclusively found in young children. Transcatheter intracranial vascular embolization (TIVE) is one of the main treatments for Rb, and to assure smooth operation, general anesthesia and MV are compulsory during TIVE. Given TIVE is usually performed time and time again to help attenuating cancer

growth and delaying the diseased eye removal, we can infer the influence of MV on infant lung development by analyzing the contribution of MV operation number, which is also the TIVE operation times, to respiratory indices, with the premise that TIVE operation duration is nearly equal when it is operated by same clinical group. Pressure-controlled ventilation is commonly utilized in pediatrics, which adjusts peak inspiratory pressure (PIP) rather as needed to meet oxygenation and ventilation goal. Under same PIP setting, will tidal volume ( $V_t$ ), mean airway pressure (MAP) be variable based largely on the patients' respiratory mechanics like lung compliance and airway resistance. Therefore, how previous MV affects the alveolar stage of lung development can be partly indicated by analyzing and comparing indices like  $V_t$ , MAP and lung compliance when collected under same ventilator settings in later MV.

### **Research process and method**

As mentioned, general anesthesia and MV is compulsory during TIVE for young children to assure a successful and safe operation, considering their poor medical compliance. Thus, our research will not cause extra intervention to the surgery, and study approach is described as follow.

All the anesthesia and ventilation performance will be conducted by a fully qualified senior anesthesiologist to assure standardized and safe anesthesia, ventilation and operation procedure. After induction of anesthesia, Rb patients will be mechanically ventilated for respiratory support. As it is recommended in the guidance of Mechanical Ventilation in Neonates and Children ([https://doi.org/10.1007/978-3-030-83738-9\\_8](https://doi.org/10.1007/978-3-030-83738-9_8)), pressure-controlled ventilation is utilized for pediatric patients with PIP adjusted around a reasonable range to meet oxygenation and ventilation goal. Moreover, inspiratory time, ventilation rate, positive end-expiratory pressure, and oxygen concentration will be set consistently among patients in appropriate range. When PIP is adjusted, indices including tidal volume, lung compliance, mean airway pressure on ventilator screen will change and be record when stable. Other datas including patient characteristics (e.g. age, gender, height and weight) and sugery information (total operation number, date of each operation) will also be recorded to help analyze.

The respective contribution of PIP, operation number, age and body mass index (BMI) to  $V_t$  per BMI, pulmonary compliance and MAP will be quantified as estimate with their significance (showed as p value), which can be obtained by regression analysis through statistical software SPSS Statistics.

**Research significance**

Considering normal lung structure with healthy function is of significant importance to physical fitness, life quality and even longevity, your generous support will help us to understand the effect of MV on lung development of alveolar stage, which will potentially optimize MV for pediatric patients and prevent ventilator induced infant lung injury.

**Privacy policy**

Your privacy will be protected as patients' medical-seeking detail and personal information will be kept confidential. If you have any question, please consult Dr. Xu via phone or email (phone number: 086-021-2507; email adress: xuchufan@alumni.sjtu.edu.cn) for more detail.

**Signature**

I understand the information printed on this form. My questions so far have been answered. I agree to take part in this study.

Signature

Date