Research Protocol

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

PROTOCOL ID: XH-21-12

NCT number: /

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

INVESTIGATOR: Chufan Xu

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1. Patients recruitment

Research protocol was approved by Xinhua Hospital Ethics Committee Affiliated to Shanghai Jiao Tong University School of Medicine. With written informed consents given by guardians of retinoblastoma (Rb) patients who undergo transcatheter intracranial vascular embolization (TIVE), patient characteristics, surgery information and mechanical ventilation (MV) indices will be collected.

Inclusion Criteria is shown as follow:

- Age 0~3;
- History of full-term birth;
- Normal physical development in height and weight;
- Supine position during operation;

Participating subjects with any one of criteria shown as follow will be excluded:

- Congenital pulmonary dysplasia;
- Current or previous lung disease;
- Chest deformity;
- Additional interference to pulmonary breathing except MV during data collection;
- being involved in other clinical subjects.

2. Mechanical ventilation and data collection

After induction of anesthesia, Rb patients will be transorally intubated and mechanically ventilated. The inspiratory time, ventilation rate, positive end-expiratory pressure, and oxygen concentration will be set consistently among patients. When anesthesiologist switches the peak ventilating pressure (PIP) around a reasonable range, indices including tidal volume, lung compliance, mean airway pressure on ventilator screen will change and be record when stable. All the ventilator setting parameters will be set according to the guidance of mechanical ventilation in neonates and children (https://doi.org/10.1007/978-3-030-83738-9_8). All the anesthesia and ventilation performance will be conducted by a fully qualified senior anesthesiologist to assure standardized anesthesia, ventilation and operation procedure. Data that this research plan

to collect can be divided into 3 categories,

- Patient characteristics, including age in days, gender, height and weight;
- Surgery information, including total number of operation and date of each operation,
- Mechanical ventilation information, including ventilation duration, tidal volume (Vt), lung compliance, mean airway pressure (MAP) and peak pressure (PIP).

3. Statistical analysis

The respective contribution of PIP, operation number, age and body mass index (BMI) to Vt 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. $P < 0.05$ is considered as statistically significant criteria.