Transnasal Humidified Rapid-Insufflation Ventilatory Exchange (THRIVE) Use in Pediatric Populations

Scientific Protocol

NCT03430206

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1) Name of study

Transnasal Humidified Rapid-Insufflation Ventilatory Exchange (THRIVE) Use in Pediatric Populations

2) PI and other key investigators or key study personnel

Thomas Caruso – PD

Chi-Ho Ban Tsui – COPD

Curtis Darling – other personnel

Alexandria Joseph - other personnel

Anthony Anderson - other personnel

Ellen Wang – other personnel

Romy Yun – other personnel

Samuel Rodriguez - other personnel

3) Specific source of institutional funding (account number)

none

4) List of sources from whom you are seeking funds (or have sought funding) for this project

none

5) Specific aims and basic hypothesis including an explicit primary hypothesis or goal

Hypothesis: The application of THRIVE at 1-2L/kg/min up to 70L/min will reduce to incidence of desaturation events (defined by SpO2 <90%) by 75%.

Secondary aims: to verify the safety of intraoperative use of THRIVE in pediatric populations in the operating room and assess the incidence of adverse effects.

6) General background (2 page maximum including published preclinical and animal data supporting basic hypothesis, if relevant)

The introduction of high-flow nasal cannula (HFNC) as Transnasal Humidified Rapid-Insufflation Ventilatory Exchange (THRIVE) to the operating theater has been demonstrated and validated in numerous studies in both adult and pediatric patients prior to intubation.[1,2,3] It has including those undergoing laryngeal procedures and surgeries, to augment sedation-related hypoventilation, or as a substitute for apneic oxygenation, intermittent intubation or mask ventilation, or jet ventilation.[4,5,6] Given the previously demonstrated safety and efficacy of high-flow nasal cannula in similar populations, we intend to study its use during relevant procedures.

7) Preliminary unpublished data (1 page maximum)

At Lucile Packard Children's Hospital in 2017, a retrospective analysis of 3 months of eligible cases (pediatric patients undergoing microdirect laryngoscopy and bronchoscopy (MDLB) with or without other airway interventions in pediatric patients undergoing general anesthesia with a

natural airway) was performed and demonstrated that 54.5% (24/44) experienced at least one desaturation value below 90%, and 29.5% (13/44) experienced at least one desaturation below 80%. Given the incidence of desaturation events of 54.5% and serious desaturation events of 29.5%, it is clear that the current methods utilized to oxygenate patients undergoing these procedures may have the potential for improvement.

8) Experimental design and data analysis, including inclusion and exclusion criteria, statistical basis for the number of subjects to be enrolled, the statistical plan for analyzing at least the primary hypothesis, matrix showing procedure plan for each study visit, data safety monitoring plan (4 pages maximum)

We aim to enroll approximately 40 pediatric patients scheduled to undergo otolaryngologic or endoscopic surgeries or procedures under general anesthesia. At the time of enrollment, patients will be randomized to control or intervention arms using a random number generator.

The incidence of desaturation events <90% during microdirect laryngoscopy procedures under general anesthesia at our institution over the previous 3 months has been reviewed and found to be 54.5% of cases. Given an estimated reduction in desaturation events by approximately 75%, we will plan to enroll a total of 40 patients (20 in each arm) for a power of 80%.

Inclusion criteria: Pediatric patients <18yo undergoing general anesthesia for procedures or surgeries at Lucile Packard Children's Hospital.

Exclusion criteria: Pregnancy, absence of parent or legal guardian able to provide written consent for study participation, anatomical or surgical contraindications (epistaxis, basilar skull fractures or abnormalities, nasal surgery or obstruction, nasal fractures, nasal vascular abnormalities), congenital heart disease with admixture physiology, baseline oxygen saturation < 94%, emergent surgery for which application of HFNC might delay surgery or might result in increased aspiration risk.

9) Significance (1 paragraph or less)

With this study we hope to determine whether THRIVE is superior to current oxygenation and ventilation techniques utilized during general anesthesia without an advanced airway device, and determine whether the use of THRIVE can prevent adverse events such as oxygen desaturation and its sequelae. We also hope to verify the safety of the use of HFNC during general anesthesia in pediatric patients.

10) Key references

1. Humphreys S, Rosen D, Housden T, et al. Nasal high-flow oxygen delivery in children with abnormal airways. Paediatr Anaesth 2017; 27(6):616-620

2. Doyle AJ, Stolady D, Mariyaselvam M, et al. Preoxygenation and apneic oxygenation using Transnasal Humidified Rapid-Insufflation Ventilatory Exchange for emergency intubation. J Crit Care 2016;36:8-12

3. Mir F, Patel A, Iqbal R, et al. A randomised controlled trial comparing transnasal humidified rapid insufflation ventilatory exchange (THRIVE) pre-oxygenation with facemask pre-oxygenation in patients undergoing rapid sequence induction of anaesthesia. Anaesthesia 2017; 72(4):439-443

4. Humphreys S, Lee-Archer P, Reyne G, et al. Transnasal humidified rapid-insufflation ventilatory exchange (THRIVE) in children: a randomized controlled trial. Br J Anaesth 2017; 118(2):232-238

5. Gustafsson IM, Lodenius A, Tunelli J, et al. Apnoeic oxygenation in adults under general anaesthesia using Transnasal Humidified Rapid-Insufflation Ventilatory Exchange (THRIVE) – a physiological study. Br J Anaesth 2017; 118(4):610-617

6. Desai N, Fowler A. Use of Transnasal Humidified Rapid-Insufflation Ventilatory Exchange for Emergent Surgical Tracheostomy: A Case Report. AA Case Rep 2017; 9(9):268-270