16.3

Research Protocol – PEDIATRIC PREHOSPITAL AIRWAY RESUSCITATION TRIAL (PEDI PART)



- **1. Purpose:** This is a multi-center study designed to determine the best airway management strategy for children under age 18 requiring life-saving care by EMS personnel.
 - Phase 1 Proposed start date: May 2024
 Patients will be randomized to Bag Valve Mask (BVM) only vs. BVM followed by a supraglottic airway.
 - Phase 2 (Start date TBD)

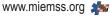
Patient will be randomized to superior method from Phase 1 or BVM followed by endotracheal intubation.

RECOGNIZE

- 2. Indications:
 - Inclusion criteria. Follow procedures below for randomization and reporting if <u>all</u>
 of the following criteria apply:
 - At least 1-day-old and less than 18-years-old
 - Cardiopulmonary arrest, major trauma, or respiratory failure
 - Life-saving care initiated or continued by Pedi-PART EMS personnel
 - Requiring active airway management (BVM or higher level of respiratory support)
- 3. Contraindications:
 - Exclusion criteria. Follow relevant Maryland Medical Protocols for EMS if any of the following criteria apply:
 - Patient is a prisoner or under arrest
 - Patient is known to be pregnant
 - Patient has a tracheostomy in place
 - Patient has a DNR/DNI (MOLST) order in place
 - Another agency initiates care
 - Parent/Guardian verbalizes objection to research or this study
 - O Paramedic does not need to discuss the study with the patient/parent/ guardian as this would interfere with the timeliness of life-saving patient care
 - O Research study staff will contact family after patient is stabilized

RANDOMIZE

- 4. Procedure: (Phase 1: BVM alone vs BVM + iGel)
 - Apply Defibrillation pads and attach end tidal CO₂ sensor
 - Follow Maryland Medical Protocols for EMS for all other interventions
 - Apply randomized airway strategy: (BVM only vs. BVM followed by iGel)
 - Even day of the week 7 a.m.-7 a.m.: Initiate BVM and continue to hospital arrival
 - Odd day of the week 7 a.m.-7 a.m.: Initiate BVM while preparing for supraglottic airway (iGel placement). Place iGel to provide oxygenation/ventilation.
 - Patient safety and the patient's medical needs should always be prioritized
 - Paramedic can override randomized intervention if deemed medically necessary
 - If unable to achieve adequate oxygenation and ventilation for your patient, despite attempts at correcting issues, paramedic should abort research protocol and follow *Maryland Medical Protocols for EMS* airway management procedures



163

Research Protocol: Pediatric Prehospital Airway Resuscitation Trial (PEDI PART) 16.3

Research Protocol – PEDIATRIC PREHOSPITAL AIRWAY RESUSCITATION TRIAL (PEDI PART) (continued)

REPORT

5. Reporting

- Complete eMEDS® report
 - Document airway management details and any adverse events or safety events and time; or clarify if occurred before, during or after the airway intervention Examples of adverse/safety events include: hypoxia, bradycardia, hypotension, regurgitation, trauma to the airway.
- Save your cardiac monitor file
- Complete electronic paramedic self-report (Scan QR code-posted in ambulance) and answer questions

CONTACT

If you have urgent questions or concerns about the study procedures or a patient enrolled in the study, please call the Children's National Emergency Medicine study team at:

Day: 202-476-8877Night: 202-924-0557

