A Novel Negative Pressure Isolation Device Reduces Aerosol Exposure: A Randomized Controlled Trial

Study Protocol and Statistical Analysis Plan

Trial Registration: ClinicalTrials.gov, NCT 04864236

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Inclusion criteria:
Adult patients (age>18) undergoing elective surgery requiring general endotracheal anesthesia

Exclusion criteria:
Patients with BMI > 40 kg/m2, or
Patients predicted to be difficult mask ventilation or intubation (as determined by anesthesiologist), or
Patients refusing to consent for any reason (ie. claustrophobia or inability to cooperate).

Preoperative:
Patients will be screened and identified by the study team and allocated to each group via simple randomization (1:1), which will occur as soon as the OR schedule is available for viewing.

Patients will be randomized to either device or no device. The study investigator will obtain consent the day of surgery. Also at the time of randomization, the anesthesia providers involved will be informed and asked to review the study protocol. Only the study investigators will be involved in the use of the device during patient care.

On the day of surgery, the primary anesthesia provider will be provided with the unassembled device (if assigned to the device group) and be asked to assemble it. This process will be observed and timed by a study coordinator.

Intubation:
For device group: one of the study investigators will place the device around the patient's head. At this time, one particle counter will be positioned on an IV pole next to the study investigator at the level of his/her nose. A second particle counter will be positioned next to the patient's head in order to take measurements from inside of the device. The study team will obtain baseline measurements from both inside and outside the device simultaneously. At the start of preoxygenation (routine part of anesthesia), the study team will begin nebulizing 5ml of saline using a standard nebulizer at 5 liters per minute of oxygen flow. A study team member will be holding the nebulizer close to the patient's nose and mouth. This will simulate airborne contamination that is generated by the patient. During this process, the patient will be instructed to breathe normally for 1 minute, then breathe deeply for 1 minute, and then breathe normally again for 1 minute. During intubation (routine part of anesthesia), the nebulizer will be placed next to the patient's head and it will be kept on until after the patient has been intubated. Concurrent with the start of preoxygenation, the particle counter will start measuring particle counts. 1 minute after the endotracheal tube or laryngeal mask airway is secured, the anesthesia provider will be instructed to remove the device. A study coordinator will record particle counts continuously until 2 minutes after the device is removed from around the patient's head.

For no device group: exactly the same except no device will be placed around patient's head.

Digital recordings of the particle counts and distribution of particle sizes will be recorded during the conduct of the study in the operating room. These recordings will not be stored with any personally identifiable information. These recordings will be stored on a secure laptop

(university-owned and encrypted) that is accessible only to the study investigators. If the participant decides to withdraw from the study, the study investigators will destroy the recordings immediately.

Statistical Methods:
Primary outcome: particle count measurements during intubation

Statistical analysis plan:
Particle counts will be compared between groups (device vs no device) using an independent samples t-test (or Wilcoxon Rank Sum Test if distributional assumptions are violated).

Power/sample size:
1) From a statistical perspective, a sample size of 10 per group allows us to detect an effect size as small as 1.35 between groups (using a t-test, >80% power, two sided alpha 0.05). A similar study (17) exploring the effectiveness of several different containment devices on airborne particles in similar settings mentioned an effect size of 1.0 (20,000 particles vs 12,000, SD of 8,000). We hypothesize that our device will be more effective than any device tested in this previous study at reducing airborne contamination so this is a conservative estimate of what we expect to see with our device.
2) Ultimately, we envision a final sample size of 50 per group to better assess both efficacy of the primary outcome as well as increase reliability in our secondary outcomes. This sample size will allow us to detect effect sizes as low as 0.57 between groups (using a t-test, >80% power, two sided alpha 0.05) and gives us a measure of precision of a confidence interval for the mean on our primary outcome of within +/-2,273 particles assuming the box group is 12,000 with a SD of 8,000.(17)

Secondary outcomes:
time to intubation (defined as time from the first entry of laryngoscope into pt's oropharynx to the time of confirmed successful tracheal intubation),
total number of intubation attempts,
pre-op airway assessment (Mallampati score and thyromental distance),
laryngoscopy grade view (Cormack-Lehane) obtained during intubation

Analysis plan:
Secondary outcomes will be compared between groups (where possible) using an independent samples t-test (or chi-square test) as appropriate.