INTELLiVENT Automated Ventilation

ClinicalTrials.gov Link: NCT04400643

<table>
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<tr>
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<tbody>
<tr>
<td>Project Title</td>
<td>Prospective, multicenter, randomized, controlled study comparing efficacy and safety of INTELLiVENT-ASV versus Non-automated Ventilation in adult ICU patients</td>
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<td>Study Population</td>
<td>Adult patients admitted to ICU Recently started on mechanical ventilation expected to last for at least an additional 24 hours.</td>
<td>Treatment Summary</td>
<td>Randomised to</td>
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<td>1. Automated ventilation with INTELLiVENT-ASV for up to 28 days</td>
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<td>2. Non-automated ventilation for up to 28 days</td>
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| Project Summary          | COVID-19 is a disease caused by a novel coronavirus (SARS-CoV-2) that causes acute hypoxemic respiratory failure and associated morbidity and mortality. There is currently no vaccine to prevent SARS-CoV-2 infection or agent to treat COVID-19; similarly, there are no approved therapeutics to treat ARDS. The most effective treatments for ARDS are ventilatory strategies. INTELLiVENT-ASV is a software accessory that automatically adjusts ventilation and oxygenation variables to keep the patient within clinician-set target ranges, from intubation until extubation. The INTELLiVENT-ASV is a closed-loop ventilation mode and is intended as an accessory for currently marketed Hamilton Medical ventilators.

INTELLiVENT-ASV includes the following features:

1. Ventilation controller (% MinVol)
2. Oxygenation controller (FiO2 & PEEP)
3. Quick Wean

With INTELLiVENT-ASV, the clinician sets patient targets for PetCO2 and SpO2 and selects the patient’s initial respiratory condition (normal lung, Acute Respiratory Distress Syndrome (ARDS), chronic hypercapnia or brain injury). The system automates the controls for CO2 elimination (%MinVol) and oxygenation (PEEP and FiO2) based on these targets and on the monitoring input from the patient (PetCO2 and SpO2). INTELLiVENT-ASV continuously monitors patient conditions and safely adjusts parameters to keep the patient within the predefined target ranges, with minimal clinician interaction, from intubation until extubation.

This is a prospective, multicenter, randomized (1:1), controlled study. This study is single-blind because only the patient will be unaware of the ventilation modality administered. The reference treatment used for comparison is a combination of controlled modes for passive patients (volume control or pressure control) and assisted/spontaneous modes for active patients (synchronized intermittent mechanical ventilation or pressure support).

Key Inclusion criteria

1. Age  ≥ 21 years old
2. Weight > 40 kilograms
3. Under invasive ventilation for less than 24 hours
4. Expected to be mechanically ventilated for at least 24 hours after enrollment

Key Exclusion Criteria

1. Fulfilling weaning criteria according to the weaning procedure of the ICU
2. Need for “rescue therapy” (ECMO, ECCO2R, HFO, etc.)
3. Arterial hypoxia due to a non-pulmonary condition (right-to-left shunting due to congenital disease, hepato-pulmonary syndrome, etc.)
4. Broncho-pleural fistula
5. Chronic or acute dyshemoglobinenia: acute CO poisoning, meth-hemoglobin, sickle cell disease.
6. Respiratory drive disorder (Cheyne-Stokes breathing) or chronic respiratory failure requiring long term invasive ventilation;
7. Moribund patient: death expected within 24 hours; Brain death status
8. Pregnancy

Co-enrollment in other trials permitted?

Co-enrollment is permitted with interventional drug studies but not permitted with other interventional device studies.