WINDSURFER TRIAL INFORMATION SHEET

WIN ratio analysis to Determine a strategy of non-invasive SUpport for Respiratory Failure in the EmeRgency Department

For hypoxemic patients in the ED, does HFNO or BiPAP lead to better outcomes?

WINDSURFER patients will be enrolled under **Exception from Informed Consent (EFIC)** due to the urgent need to initiate NIRS in patients with hypoxemia.

Study Intervention

The two strategies of NIRS we will compare:
(1) Heated Humidified High-Flow Nasal Oxygen (HFNO)
(2) Non-Invasive Positive Pressure Ventilation using bi-level positive airway pressure (BiPAP)

We will randomize 500 adult ED patients with AHRF to 24 hours of NIPPV or HFNO.

Patients should remain on assigned NIRS strategy for 24 hours or until liberation, intubation, or death. Avoid crossing the patient over to the unassigned NIRS strategy for >2 hours total during the 24 hours.

Call the WINDSURFER team for patients who meet the following criteria:

- ☑ 18 years or older
- ☑ In the ED
- ☑ Acute hypoxemic respiratory failure
  - Respiratory rate ⩾25 **AND**
    - Requires ⩾6 liters/min oxygen to maintain SpO2 >90% **OR**
    - S:F <250

    OR
  - Arrival at ED on prehospital NIRS
- ☑ Clinical need for NIRS: the physician determines that NIRS is needed as soon as possible based on tachypnea, hypoxemia, or work of breathing
- ☑ Can be randomized within 2 hours of identification of need for NIRS (goal is within 1 hour).
- ☑ Can be randomized within 6 hours of ED arrival/triage

Frequently Asked Questions

Enrollment & Timing

Should I wait until I know the diagnosis or cause of AHRF? No. Randomize and start NIRS as soon as possible after the clinician identifies the need for NIRS, aiming for 15 minutes to 1 hour (at most).
Do I need to wait to start NIRS until the patient is randomized? If necessary, you may start NIRS while waiting for randomization. The patient may be switched to the assigned treatment once randomized.
What is the purpose of a 6-hour window after ED arrival? This allows for patients who deteriorate while in the ED.

Exception from Informed Consent (EFIC)

If an LAR is present, why use EFIC rather than a formal informed consent process? Subjects in WINDSURFER must be enrolled as soon as possible after need for NIRS is identifies. Research teams will fully inform family members after enrollment.

Intubation

Does the protocol require intubation based on specific parameters? We recommend thresholds for intubation based on patient physiology. Decision and timing of intubation is determined by the treating team.

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Treatment Selection & Clinical Equipoise

Don't COPD, heart failure, and "SCAPE do better with NIPPV than HFNO? In these conditions NIRS is supportive - not therapeutic. Recent trials (RENOVATE) suggest that HFNO and NIPPV are equally effective in these conditions.

What about patients with chronic respiratory failure due to conditions like obesity-hypoventilation (OHS) and neuromuscular disorders (NMD)? Patients on home NIPPV (e.g., BiPAP or AVAPS) for chronic respiratory failure should be excluded. All other OHS and NMD are eligible for the trial

Management During the 24-Hour Study Period

What NIRS strategy should I use during the first 24 hours, and what happens after 24 hours? During the first 24 hours the patient should remain on the assigned NIRS strategy unless they are liberated from NIRS, intubated, or die. After 24 hours treatment is at the discretion of the clinical team.

Can the patient crossover to the alternate NIRS strategy? Patients should stay on the assigned treatment. A patient may spend no more than 2 hours total on the alternate treatment assignment.

What happens if the accepting team wants to change from the NIRS strategy based on an opinion that NIPPV or HFNO is better, or because it facilitates bed placement? While individual opinions may be strong, current published evidence does not show that either NIPPV or HFNO is better in patients with AHRF, especially those with heart failure or COPD comorbidities. Patients should stay on the assigned treatment.

If the patient is on CPAP at home for nighttime obstructive sleep apnea, should I put them on CPAP at night in the hospital? No. Continue the assigned NIRS strategy for 24 hours, including at night. Nocturnal CPAP is not a support for patients with hypoxemic respiratory failure.