

Reestablishing Sleep and Circadian Alignment in Medical Intensive Care Unit (MICU) Patients Via a Mechanistic RCT of an Sleep Chronobundle

NCT05551325

Status	RECRUITING
Phase	Not Applicable
Sponsor	Yale University
Enrollment	160 participants

Key Eligibility Criteria

Inclusion (2)

- Critically ill patients admitted to the MICU who require mechanical ventilation, noninvasive ventilation, high flow nasal cannula, or vasopressor support and who remain on qualifying support as of 09:00 on study randomization day. Randomization will occur on the second or third calendar day following MICU admission. MICU admission must have occurred within 24 hours of hospital admission.
- Age greater than or equal to 18 years old.

Exclusion (12)

- Not expected to remain in the MICU for at least 48 hours post-randomization.
- Imminently dying or with a hospice status.
- At significant risk for pre-existing circadian abnormalities including: (1) severe chronic brain injury (injury greater than 30 days ago resulting in the inability to live independently); (2) acute brain injury of any severity that is reasonably expected to impact the central circadian clock (e.g., cardiac arrest); (3) documented circadian disorder (<1% population) or blind/disease of the optic nerve; (4) current or recent (last 1 year) shiftwork; and (5) homelessness, incarceration, or institutionalization.
- At elevated risk of aspiration due to structural or functional abnormality of the gastrointestinal tract OR fed via enteral nutrition (e.g., "tube feeds") prior to ICU admission.
- Admitted to the ICU for treatment of diabetic ketoacidosis or hyperosmolar state; this diagnosis will be established via review of the medical record for a description of diabetes in the past medical history or the presence of diabetes medication on the confirmed home medication list AND hyperglycemia attributed to diabetic ketoacidosis or diabetic hyperosmolar state by the admitting care team in their written assessment of the patient.

... and 7 more (see full listing online)

Locations (2 total)

Yale New Haven Hospital Medical Intensive Care Unit (YNHH MICU) at St Raphael's Campus, New Haven, Connecticut, United States

Yale New Haven Hospital Medical Intensive Care Unit (YNHH MICU) at York Street, New Haven, Connecticut, United States

<https://clinicaltrials.gov/study/NCT05551325>

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