PATIENT VENTILATOR ASYNCHRONY IN CRITICALLY ILL CHILDREN - PROSPECTIVE OBSERVATIONAL STUDY

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Specific Aim 1) To identify the frequency and risk factors for PVA and its subtypes in ventilated children, with a specific focus on DC breaths. Hypothesis: PVA subtypes related to inadequate ventilator support (flow undershoot and premature cycling...

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON56470

Source
ToetsingOnline

Brief title
PVA

Condition

- Respiratory disorders NEC

Synonym
acute lung injury, Respiratory failure

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: NIH/NHLBI

Intervention

Keyword: Children, Mechanical ventilation, Patient ventilator asynchrony

Outcome measures

Primary outcome

To identify the frequency and subtypes of PVA, as well as to train and validate

machine learning models.

Secondary outcome

Not applicable

Study description

Background summary

Patient ventilator asynchrony (PVA) is common but infrequently identified in children. Pre-clinical studies show a clear causal relationship between certain PVA subtypes and ventilator induced lung injury, diaphragm dysfunction, and delirium. PVA may exacerbate ventilator induced lung injury (VILI), particularly if PVA results in a double-cycled (DC) breath. DC breaths imply that a second breath is delivered by the ventilator before the patient has fully exhaled. Double cycled breaths (DC) are particularly injurious because the resultant breath stacking causes unintentionally large tidal volumes and trans-pulmonary pressures, which exacerbates regional overdistension of the lung, and is associated with mortality in adults with ARDS.

Study objective

Specific Aim 1) To identify the frequency and risk factors for PVA and its subtypes in ventilated children, with a specific focus on DC breaths. Hypothesis: PVA subtypes related to inadequate ventilator support (flow undershoot and premature cycling) and reverse triggering will be the most common causes of DC breaths, with risk factors related to respiratory drive and ventilator settings.
Specific Aim 2) To develop and test a clinical decision support system using machine learning techniques to automatically identify common forms of PVA in children. Hypothesis: (a) Machine learning models using waveforms available on all mechanical ventilators will accurately identify PVA subtypes compared to gold standard annotations which include measures of neural drive. (b)

Algorithms can be optimized for high sensitivity and low false alert rates to identify children with frequent PVA.

Study design

Multi-center prospective observational cohort.

Study burden and risks

Minimal. For this study, no deviation from standard care will occur. Data will be collected from the mechanical ventilator. sEMG electrodes will be used to quantify the electrical activity of respiratory muscles.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Babies and toddlers (28 days-23 months)
Newborns

Inclusion criteria

age > 37 weeks CGA to 18 years
anticipated to be mechanically ventilated for at least 24 hours within 96 hours
of initiation of invasive mechanical ventilation

Exclusion criteria

Serious skin defects that prevent sEMG stickers from being placed

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2023
Enrollment:	70
Type:	Anticipated

Ethics review

Approved WMO

Date:	29-01-2024
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL85342.042.23