Study Protocol and Statistical Analysis Plan

Official Title: Relationship Between Electrical Impedance Tomography (EIT) Measurements and Parameters of Respiratory Status in Very Preterm Infants: An Observational Cohort Study

ClinicalTrials.gov Identifier: NCT06609135

Sponsor: Lawrence Rhein

Responsible Party: Lawrence Rhein, University of Massachusetts, Worcester

Document Date: June 20, 2023

1. Study Overview

This is a prospective, single-center, observational cohort study conducted at the UMASS Memorial Medical Center NICU. The study investigates the use of Electrical Impedance Tomography (EIT) to assess respiratory status in very preterm infants, and its potential predictive value for the successful discontinuation of respiratory support at key developmental timepoints.

2. Study Design and Participants

• Design: Prospective observational cohort

• Setting: UMASS Memorial Medical Center NICU, Worcester, MA

• Study Start: November 4, 2023

• Completion Date: August 31, 2024

• Enrollment: 20 infants

Inclusion Criteria:

• Infants born between 25+0 and 29+6 weeks gestational age

• Admitted to UMass NICU

Exclusion Criteria:

• Major congenital anomalies

• Severe hemodynamic instability

3. Interventions and Devices

• Device: Sentec LuMon Electrical Impedance Tomography (EIT) system

• Device: Sentec Digital Monitoring System (transcutaneous CO_2 monitor)

EIT and CO_2 monitoring were performed at least twice weekly, ideally daily, starting from consent through NICU discharge.

4. Study Procedures

EIT monitoring began at 28+0 weeks PMA or 7 days postnatally (whichever came later), and was repeated weekly until NICU discharge. Sessions lasted 3 hours and were timed between feedings to reduce motion artifacts. Data were stored securely after each session.

5. EIT Metrics and Analysis

EIT data were analyzed breath-by-breath to derive the following parameters:

• FLS (Fraction of Lung Signal) – proxy for lung recruitment

• GI (Global Inhomogeneity Index) – indicator of ventilation uniformity

• CoV, EELI, and EILI were evaluated but not selected due to variability and artifacts GI was post-processed by Sentec; FLS was computed in-breath using standard software.

6. Study Outcomes

Primary Outcome

• Association of FLS and GI at 31+0 weeks PMA with successful CPAP discontinuation at 32+0 weeks PMA

Secondary Outcomes

1. Prediction of CPAP discontinuation at 33+0 weeks PMA based on EIT metrics at 32+0 weeks

2. Association of metrics at 34+0 weeks PMA with CPAP independence by 36+0 weeks

3. Exploratory:

• Correlation between EIT and transcutaneous CO_2 levels

• Correlation with time to full oral feeds

• Association with BPD status at 36+0 weeks PMA

7. Statistical Analysis Plan

• T-tests for continuous variables (e.g., FLS, GI vs. CPAP outcomes)

• Fisher’s exact tests for categorical demographic characteristics

• Missing data were handled via complete case analysis

• No imputation was applied

• Sample size (n=20) limits power; analyses are considered exploratory

8. Limitations

• Missing data due to timing of enrollment and technical failures

• Only 3/6 weaned infants and 8/14 non-weaned infants had usable data at 31 weeks

• At 33 weeks: 4/14 missing; at 36 weeks: 3/10 missing

• Measurement variability due to EIT belt placement, gel quality, motion, and interference

• Small sample size limits statistical power and generalizability

• Demographic imbalance (e.g., GA, weight) not controlled