The Canadian Neonatal Network™/Le Réseau Néonatal Canadien™
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Research Proposal

Early Prophylactic CPAP in Spontaneously Breathing Late Preterm Newborn Infants Born by Cesarean Delivery

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Background

Preterm infants born between account for a majority of Neonatal Intensive Care Unit (NICU) patients (n= 5234 within CNN in 2022), who have a high rate of respiratory morbidities compared to term infants (Raju 2006). The sheer numbers of late preterm infants have a major impact on neonatal resource utilization. Continuous Positive Airway Pressure (CPAP) provided constant distending pressure to the airways of a spontaneously breathing baby throughout the respiratory cycle and has been shown to improve survival without bronchopulmonary dysplasia in extreme and moderate preterm infants (Schmölzer 2013, Subramaniam 2016). Extrapolated from this evidence, there has been progressively increased use of CPAP among late preterm newborn infants (Hishikawa 2016, Smithhart 2019, Shah 2019). A recently performed International Liaison Committee on Resuscitation (ILCOR) systematic review and meta-analysis included two randomized controlled trials (Celebi 2016, Osman 2019), which showed early CPAP decreased the likelihood of NICU admissions and respiratory support after NICU admission with no increased incidence of air-leak syndromes.

Research Gap

The optimal respiratory support during initial stabilization after birth for infants born at 32^{+0}-36^{+6} weeks' gestation at birth is unknown.

Preliminary Data

In 28 (n=13, CPAP for 20 min; n=15, no CPAP) infants born via elective cesarean delivery, the proportions who had respiratory support after NICU admission were 2/13 with CPAP for 20min vs. 7/15 with no CPAP, p=0.114), which suggests that CPAP for 20min might reduce respiratory support after NICU admission.

Rationale

The optimal respiratory support during initial stabilization after birth for infants born via cesarean delivery at 32^{+0}-36^{+6} weeks' gestation at birth is unknown and therefore, they are at risk of worse neonatal outcomes without examining the optimal respiratory support.

Hypothesis(es) and Aims

Hypothesis: In infants born between 32^{+0}-36^{+6} weeks' gestation via cesarean delivery at birth does CPAP for 20min compared to standard of care reduces the need for ongoing breathing support during NICU admission?
Aim: To evaluate the effects of commencing respiratory support with CPAP at birth compared with no CPAP in preterm infants born between 32^{+0}-36^{+6} weeks' gestation born via cesarean delivery.

Design

Unblinded, multi-center, randomized trial in preterm babies born between 32^{+0}-36^{+6} weeks of gestation born via cesarean delivery in Level II and III hospitals across Canada. Exclusion criteria include major congenital abnormalities and vaginal delivery. Individual randomization to CPAP or no CPAP. The primary outcome will be rate of respiratory support within the first 7 days of NICU admission. Treatment Pathways: Pathway A: CPAP for 20 min after initial stabilization, Pathway B: Standard of care, according to local policy.

Sample Size

The sample size is based on the primary outcome, respiratory support within the first 7 days of NICU admission, which occurs in 46% (control), to achieve an estimate reduction of 10% (in the intervention group to 41%), we need ~1,200 infants with 80% power and 5% alpha.

Other Considerations

There is very limited data in this infant population (32^{+0}-36^{+6} weeks' gestation), which leaves the target population without evidence for the optimal respiratory support after birth. Our team has extensive experience in performing these trials, which will allow for completion of the trial in the proposed time frame.