2025

MONTREAL CHILDREN'S HOSPITAL (MUHC)

NICU RESEARCH STUDIES

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MONTREAL CHILDREN'S HOSPITAL WEBSITE

DOPAMINE VS NOREPINEPHRINE

Project Title: Dopamine vs. Norepinephrine for Hypotension in Very Preterm Infants with Late-onset Sepsis: A National Comparative Effectiveness Research (CER) Project

Type of study: National comparative effectiveness research (CER) study
Investigators: Dr. Gabriel Altit (MUHC), Dr. Marc Beltempo (MUHC) & External PIs
Clinical Research Coordinator: Daniela Villegas M (email: daniela.villegas.martinez@muhc.mcgill.ca)

Background: Fluid-unresponsive hypotension needing cardiotropic drug treatment is a serious consequential complication in very preterm neonates (gestational age ≤ 32 weeks) with suspected late-onset sepsis (LOS), defined for this study as culture-positive or negative bloodstream infection or necrotizing enterocolitis (NEC) occurring >48 hours of age. In Canada, ~250 very preterm neonates receive cardiotropic drugs for LOS related fluid-unresponsive hypotension every year. of these, ~35-40% die. Although the underlying pathophysiology is predominantly vasodilatory shock, unlike for adult patients, there is little evidence to inform practice.

Aim of the study: To compare the relative effectiveness and safety of pharmacologically equivalent dosages of dopamine versus norepinephrine for primary pharmacotherapy for fluid-unresponsive hypotension in preterm infants born ≤ 32 weeks gestational age with suspected LOS.

Summary of intervention: The attending team will determine the adequacy of circulation and need to initiate, escalate, as well as patient's readiness to wean and/or discontinue treatments. However, all patients deemed circulatory insufficient will receive fluid therapy either Dopamine or Norepinephrine (minimum 10-20 cc/kg).

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Sinai Health | Mount Sinai Hospital
Joseph & Wolf Lebovic Health Complex

Inclusion criteria:

- Infants born GA ≤32 weeks and > 48 hours of life.
- Infants receiving primary vasopressor therapy with Dopamine or Norepinephrine in the context of suspected late-onset sepsis or NEC with systemic hypotension.

Exclusion criteria:

- Infants with known chromosomal or genetic anomalies.
- Infants receiving primary therapy with agents other than Dopamine or Norepinephrine.

More information:
https://www.neocardiolab.com/research-recherche/dopamine-vs-norepinephrine-cer-study

THE DOXA TRIAL

Project Title: Doxapram versus Placebo Study in Premature Infants: A Double-blind Multicenter Randomized Study.

Type of study: Double-blind Multicenter Randomized international Study.
Investigators: Dr. Wissam Shalish (MUHC), Dr. Marc Beltempo (MUHC)& External PIs.
Clinical Research Coordinator: Daniela Villegas M (email: daniela.villegas.martinez@muhc.mcgill.ca)

Background: Preterm infants often suffer from apnea of prematurity (AOP; a cessation of breathing) due to immaturity of the respiratory system. AOP can lead to oxygen shortage and a low heart rate which might harm the development of the newborn, especially the central nervous system. In order to prevent oxygen shortage, infants are treated with non-invasive respiratory support and caffeine. Despite these treatments, many preterm newborns still suffer from AOP and need invasive mechanical ventilation. Doxapram is a respiratory stimulant that has been administered off-label to treat AOP.

Aim of the study: The main objective of the trial is to investigate if Doxapram is safe and effective in reducing the composite outcome of death or neurodevelopmental impairment at 2 years corrected age as compared to placebo.

Summary of intervention: All babies will receive an intravenous (IV) infusion (into the vein) of a glucose 5% solution with or without the study drug (babies in the placebo group will receive glucose 5% without the study drug added). The study drug/placebo will be administered through an IV for at least the first 24 hours. After this period, if the baby does not have an IV anymore, the study drug/placebo can be administered through a tube in the baby's stomach called a gastric tube. The baby will be treated with the study drug/placebo until the apneas have reduced in frequency and severity compared to when the study drug/placebo was initiated. Alternatively, if apneas persist and invasive ventilation is required, the study drug/placebo will be stopped. Finally, between 18-24 months, the parents will be asked to complete a questionnaire for the baby either by phone or during the standard of care visit with the baby's doctor.

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MICYRN
better health for mothers and children
CHU de Québec Université Laval
DOXA-TRIAL

Inclusion criteria:

- Gestational age at birth < 29 weeks
- Caffeine therapy, adequately dosed
- Optimal Non-invasively supported with nasal Continuous Positive Airway Pressure (CPAP) or ventilation ((S)NIPPV, NIV-NAVA, BIPAP/Duopap, SIPAP)
- Persistent apneas despite optimal caffeine and non-invasive respiratory therapy, that are close to requiring intubation and invasive ventilation as judged by the attending physician.

Exclusion criteria:

- Use of theophylline
- Chromosomal defects.
- Major congenital malformations that: compromise lung function, result in chronic ventilation; increase the risk of death or adverse neurodevelopmental outcome (congenital cerebral malformations, chromosomal abnormalities);
- Palliative care or treatment limitations because of high risk of impaired outcome.

More information:
https://clinicaltrials.gov/study/NCT04430790

THE EMBLEM STUDY

Project Title: Early-life MRI biomarkers of longer-term respiratory morbidity in infants born extremely preterm (EMBLEM)

Type of study: Multicentric Observational Prospective Study
Investigators: Dr. Gabriel Altit (MUHC), Dr. Larry Lands (MUHC), Dr. Andreea Gorgos (MUHC), Dr. Zonah Khumalo (MUHC) & External PIs.
Clinical Research Coordinator: Daniela Villegas M (email: daniela.villegas.martinez@muhc.mcgill.ca)

Background: Bronchopulmonary dysplasia (BPD) is a chronic lung disease of prematurity associated with multi-system morbidity, including neurodevelopment, that continues into adulthood. Lung disease is not easily predicted using traditional definitions of BPD; better measures are needed to define lung disease early in life and predict long-term outcomes. Pulmonary vascular changes are suspected to contribute to morbidity. Novel imaging modalities, including phase-resolved functional lung (PREFUL) and ultra-short echo time (UTE) magnetic resonance imaging (MRI), can evaluate pulmonary parenchyma and vasculature and their interplay with high resolution.

Aim of the study: To validate MRI biomarkers of pulmonary parenchymal and vascular abnormalities as predictors of respiratory morbidity and neurodevelopmental impairment (NDI) in infants born extremely preterm.

Summary of intervention: At baseline (36 weeks PMA), babies will undergo Phase-resolved functional lung and Ultra-short echo time MRI, echocardiogram, lung function (oscillometry) and lung ultrasound. We will evaluate 4 MRI biomarkers of pulmonary parenchymal and vascular structural disease. The primary outcome will be severe respiratory morbidity, evaluated up to 18 months CA through questionnaire every 3 months and chart review.

Inclusion criteria:

- Infants born at <29 weeks gestation.
- <36 weeks PMA at the moment of interventions.

Exclusion criteria:

- Known interstitial lung disease, congenital lung anomaly, ciliary dysfunction, immunodeficiency, cystic fibrosis, neuromuscular disease, or structural heart disease (other than atrial septal defect/hemodynamically insignificant ventricular septal defect/patent ductus arteriosus).
- Genetic syndrome or congenital anomaly.
- Contraindications for MRI or transport.
- Invasive or non-invasive ventilation that cannot be safely removed for MRI.
- Current respiratory infection.
- Family cannot speak English/French.
- Transferred to another hospital prior to baseline study visit.
- Not receiving follow-up at one of the study centres.

More information:
https://www.neocardiolab.com/research-recherche/emblem-study

FETAL BRAIN GROWTH

Hôpital de Montréal pour enfants
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McGill University Health Centre

Fetal Brain Growth

Project Title: Fetal Brain Growth: Effects of Antenatal Corticosteroids on Fetal and Neonatal Brain Development - a pilot study

Type of study: Observational Prospective Study
Investigators: Dr. Jarred Garfinkle (MUHC) Dr. Anne-Maude Morency (MUHC) & External PIs
Clinical Research Coordinator: Daniela Villegas M (email: daniela.villegas.martinez@muhc.mcgill.ca)

Background: In Canada, 30,000 infants are born preterm (less than 37 weeks of gestation) each year, which represents 7-8% of live births. Many more infants are exposed to threatened preterm labor (TPTL) and antenatal corticosteroids (ACS), which are given for fetal lung maturation but are ultimately born at term. There is compelling evidence that the brain of the fetus exposed to TPTL and ACS deviates from its normal developmental trajectory. Indeed, children exposed to TPTL and ACS who are ultimately born at term are at higher risk for neurodevelopmental challenges. The impact of TPTL and ACS on fetal brain development thus merits further investigation.

Aim of the study: The overall objective is to explore the feasibility of measuring fetal and neonatal brain growth using 2D and 3D ultrasound in fetuses exposed to TPTL and ACS compared to non-exposed fetuses.

Summary of intervention: Patients with singleton pregnancies on our site with repeated ultrasound measurements every 4 weeks will be evaluated for fetal brain development. The exposed group is defined as patients with a dual exposure of TPTL and ACS. The non-exposed group will be composed of patients who did not have TPTL and ACS. Therefore, patients will have a maximum of 5 additional visits (4 that will occur prenatally and 1 postnatal visit).

Inclusion criteria:
Exposed group - TPL and ACS:

- 22-34 weeks and 6 days gestation at time of recruitment.
- Threatened preterm labor (TPTL)
- Administration of a partial or full course of ACS.
- Admission to the MUHC-RVH birthing center or the antenatal floor (D6S).
- Delivery planned at the MUHC-RVH or an institution around the Greater Montreal Area.

Inclusion criteria (non-exposed group):

- At or prior to 22 weeks gestation at time of recruitment.
- Delivery planned at the MUHC-RVH.

Exclusion criteria:
For both groups

- Major congenital anomalies, suspected fetal syndrome or genetic disease, or intra-uterine fetal growth restriction.
- Significant maternal disease which may cause preterm delivery or fetal growth restriction (e.g., severe infection, uncontrolled hypertension or diabetes).
- Patients who received more than one course of ACS prior to enrollment.
- Patients on any oral or other systemic corticosteroids, with the exception of inhaled corticosteroids.
- BMI over 35.

More information:
https://classic.clinicaltrials.gov/ct2/show/NCT05994443

PARENTAL ENGAGEMENT AND WELL-BEING IN THE NICU

Project Title: Optimizing Parental Self-Efficacy in the Neonatal Intensive Care Unit: Implications on Child Care and Parenting Quality

Type of study: Multicentric Observational Prospective Study
Investigators: Dr. Tina Montreuil & internal MUHC co-investigators/collaborators.
Clinical Research Coordinator: Chloé Gratton (email: chloe.gratton@mcgill.ca)

Background: Many NICU parents feel overwhelmed and inadequately prepared to care for their often high-risk, premature infant, particularly regarding making decisions about complex medical care issues. NICU clinicians have identified the urgent need for improved mental health and emotional support for NICU parents facing these difficult challenges. The promotion of parental engagement and attachment with their infant once discharged, is a crucial component to ensure a successful transition to home and to prevent readmission. Self-efficacy and parental beliefs of competence in managing parental tasks has been thought to act as a protective factor for both parent and child's emotional well-being. It is therefore important that parents receive adequate support, particularly in the NICU, so they can in turn have the emotional availability and parenting competence to help their child thrive.

Aim of the Study: The purpose of this study is to identify the specific psychosocial and emotional needs of parents with newborns in the NICU to better understand the factors associated to parental engagement in the NICU given its implications on child care and parenting quality.

Summary of Intervention: Participants will be asked to complete a set of self-administered questionnaires pertaining to parental engagement and self-efficacy within the NICU and will be invited to take part in a qualitative interview about their experience as a parent in the NICU.

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the montreal children's hospital foundation
Childhood Anxiety and Regulation of Emotions (C.A.R.E.) Research Group

Inclusion criteria:

- Parent of a child admitted to the Montreal Children's Hospital NICU.
- Ability to read and write in English or French.
- Have a RAMQ card.

More information:
For more information, please contact the clinical research coordinator.

RESET-PDA

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Sunnybrook
HEALTH SCIENCES CENTRE

Project Title: REdefining the SignificancE and Treatment threshold for PDA in preterm neonates (RESET-PDA)

Type of study: Multicentric Observational Prospective Study
Investigators: Dr. Gabriel Altit (MUHC) & External PIs
Clinical Research Coordinator: Daniela Villegas M (email: daniela.villegas.martinez@muhc.mcgill.ca)

Background: Prior studies on the reliability of targeted neonatal echocardioraphy (TNE) in extremely low gestational age neonates (ELGANs) with a patent ductus arteriosus (PDA) have been limited to a single-center setup and an evaluation of pre-defined images by a small set of study observers. To facilitate large multicenter prospective studies, the relaibility of collecting comprehensive TNE measures across centers needs to be established.

Aim of the study: To investigate the interobserver reliability of echocardiography measures of PDA size/shunt volume, left ventricular (LV) funcion and dimensions among TNE-Neonatogists.

Summary of intervention: Four distinct, clinically relevant, and pragmatic postnatal age specific prediction models will be developed using the main study outcome, based on age of PDA evaluation after birth: (1) 1-3 days, (2) 4-7 days, (3) 8-14 days and (4) 15-28 days. Postnatal-age specific models provide a more homogeneous population for modelling and may be more applicable to clinical practice. For each model detailed clinical and imaging data from echocardiography evaluations, which identify a PDA and occur in the respective timeframe will be abstracted and included in the model.

Inclusion criteria:

- GA ≤27 weeks +6 days at birth.
- Echo with PDA diameter ≥ 1.50 mm in the first 28 days after birth.

Exclusion criteria:

- Major congenital anomaly/genetic syndrome.
- Structural congenital heart disease other than small VSD (<2 mm) or secundum ASD (irrespective of size).

More information:
https://www.neocardiolab.com/research-recherche/reset-pda-study-protocol

THE SAVING BABIES STUDY

Project Title: Sonographic Assessment Validation study for Neonatal Global health improvement

Type of study: Multicentric prospective study
Investigators: Dr. Gabriel Altit (MUHC), Dr. Michelle Ryan (MUHC), Dr. Pia Wintermark (MUHC), Dr. Wadi Mawad (MUHC), Dr. Elisa Ruano Cea (MUHC) & External PIs
Clinical Research Coordinator: Daniela Villegas M (email: daniela.villegas.martinez@muhc.mcgill.ca)

Background: Recently, wireless handheld ultrasound devices have been developed, primarily for use in adults, with some applications in older pediatric patients. However, these ultrasound solutions have not yet been validated for specific use in the neonatal context. The validation of these devices represents a unique opportunity to enhance diagnostic capabilities and monitoring at a lower cost. However, it is crucial to thoroughly assess the reliability of these devices before introducing them globally into neonatal care and research.

Ultrasound is a non-invasive and radiation-free imaging technique. It enables visualization of cardiac, vascular, cerebral, abdominal, and pulmonary structures. Its use is fundamental for the diagnosis, monitoring, targeted management, and adjustment of treatments in newborns facing postnatal complications.

Aim of the study: To validate the accuracy and reliability of measurements obtained using the hand-held ultrasound probe relative to those obtained using the standard of care advanced ultrasonography: Cardiac, lung and intracranial measurements.

Summary of intervention: Newborns of various gestational and chronological age, with various baseline diagnosis, will be recruited and scanned for lung, head, heart ultrasound using the golden standard ultrasound machine, and with the hand-held ultrasound. At a later stage, two blinded data extractors will be quantifying right and left cardiac function, lung scores, and intracranial bleed grading on the 2 modalities. Inter-rater and intra-rater variability analysis will be done. Correlation between the values and diagnosis of the two hand-held results will be compared to those of the standard ultrasound.

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CHU Sainte-Justine
Le centre hospitalier universitaire mère-enfant
Université de Montréal

Inclusion criteria:

- Newborns ranging from 23 weeks to 41 weeks + 6 days of GA.
- Newborns admitted to the NICU or nursery

Exclusion criteria:

- Infants with known genetic anomalies, congenital brain, heart, or lung defects, or those isolation for COVID-19 precaution will be excluded from the study.

More information:

https://www.neocardiolab.com/research-recherche/saving-study

THE BCPAP STUDY

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projet hôpital intelligent
smart hospital project

Project Title: The use of bubble continuous positive airway pressure in premature infants: acoustics as a metric of effective pressure delivery.

Type of study: Observational Prospective Study
Investigators :Dr. Wissam Shalish, Dr. Robert Kearney & Dr. Guilherme Sant'Anna & External PIs
Clinical Research Coordinator: Ana Saavedra Ruiz (CUSM) ana.saavedra.ruiz@muhc.mcgill.ca

Background: Infants born prematurely have lungs that are not fully developed and therefore require some form of respiratory support, such as bubble CPAP (bCPAP). The pressures delivered by the bCPAP device along with the vibrations of the bubbles can help lungs grow. For the bCPAP to work as intended, the prongs need to be placed adequately in the nares. Nevertheless, oftentimes the prongs get displaced, or the infants open their mouths, making the pressure less able to reach the lungs. Unfortunately, there are currently no methods for continuously monitoring the delivery of pressure from the bCPAP system to the infant's lungs. This means that different healthcare professionals to make sure the bCPAP is working as intended frequently check the infant. Likewise, when the bCPAP system is not bubbling, the infant might need some help to adjust their prongs or their position because they might not be receiving the desired CPAP pressures.

Aim of the study: To use the acoustic properties of the bubbling sounds (loudness and frequency of the sounds) to estimate the pressure being delivered by the CPAP system in preterm neonates.

Summary of intervention: Patients included in the Bubble CPAP study will be monitored and different signals will be acquired by different devices, depending of the group, for a total duration of 3 hours. During the study, infants will be randomized to receive their prescribed CPAP pressures at gas flow rates of 6L/min, 8L/min, and 10L/min for a period of 1 hour each.

Inclusion criteria:

- Infants on bCPAP with gestational age < 32+0 weeks.
- PMA between 28+0 and 36+6 weeks and PNA greater than 168 hours (7 days) at the time of the study.
- On bCPAP device with binasal prongs at the time of the study.
- Receiving bCPAP levels of 5 to 7 cm H2O with gas flows between 6L/min and 10L/min at the time of the study.

Exclusion criteria:

- Infants with known major congenital anomalies, heart disorders, or neuromuscular disease.
- Infants receiving ventilator-derived CPAP or CPAP via a nasal mask interface at the time of the study.
- Infants receiving inotropes, narcotics or sedative agents at the time of the study.
- Infants deemed clinically unstable for the study by the attending neonatologist.

THE DREAM:
PILOT PROJECT

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Montreal Children's Hospital
McGill University Health Centre

projet hôpital intelligent
smart hospital project

Project Title: Detection of CardioRespiratory Events using Acoustic Monitoring in Preterm Infants on Continuous Positive Airway Pressure (DREAM)

Type of study: Multicentric Observational Prospective Study
Investigators :Dr. Wissam Shalish, Dr. Robert Kearney & Dr. Guilherme Sant'Anna & External PIs
Clinical Research Coordinator: Ana Saavedra Ruiz (CUSM) ana.saavedra.ruiz@muhc.mcgill.ca

Background: In current practice, neonatal intensive care units (NICUs) around the world rely on information provided by the patient's bedside monitor to detect, describe, and manage cardiorespiratory events. The monitor captures heart rate, respiration and oxygen saturation through electrocardiography (ECG), transthoracic impedance and pulse oximetry, respectively.

Aim of the study: To describe the relationship between respiratory acoustics and airflow, and determine the reliability of respiratory acoustic monitoring at detecting breathing sounds in preterm infants.

Summary of intervention: Patients included in the DREAM study will be monitored and their vital signals measurements will be acquired using different devices by the research team for different durations, depending on the group.

Inclusion criteria:

- Infants with gestational age <32+0 weeks.
- Postmenstrual age between 28+0 and 36+6 weeks. (Different for each 3 groups of the study, for more information contact CRC).

Exclusion criteria:

- Infants with known major congenital anomalies.
- Infants with known congenital heart disorders, neuromuscular disease, diaphragmatic paralysis or a diagnosed phrenic nerve injury, history of esophageal perforation in the 7 days preceding, history of pneumothorax requiring chest tube insertion in the 7 days preceding the study.

More information:
https://clinicaltrials.gov/ct2/show/NCT05196646

THE GWS-PRAGMATIQ STUDY

Project Title: Rapid whole-genome sequencing in acute care neonates and infants

Type of study: Multicentric Observational Prospective Study
Investigators : Dr. Leora Witkowski (MUHC) & external PIs
Genetics counselor: Frédéric Coulombe (frederic.coulombe@muhc.mcgill.ca)

Background: Rare genetic disorders (RGD) and congenital malformations indicating a possible genetic syndrome affect 1-2% of live births and are the leading cause of hospitalization and death in infants in Canada. Among children admitted to neonatal or pediatric intensive care units (NICU/PICU), those with a suspected genetic disorder have a higher risk of both mortality and prolonged hospital stay. Making a genetic diagnosis in the newborn period or in the following months is especially important because RGD can evolve rapidly at this early stage of life and precise diagnosis can have critical implications for an infant or child's health for their entire life. However, there are 5,000 to 8,000 rare genetic conditions and the presentation of newborns and infants is frequently non-specific or differs from that observed in older patients, making a precise diagnosis of a RGD difficult or impossible.

Aim of the study: The ultimate objective of the proposed project is to offer, within the next three years, rapid clinical genome-wide sequencing (GWS) to all critically-ill newborns and infants who may benefit from this test in Quebec.

Summary of intervention: Once genetics consultation is requested and parents agree to the whole-genome sequencing, one blood draw from the infant and at least one from the parents will be obtained.

Inclusion criteria:

- <18 years-old admitted in one of the four pediatric university health centers in Quebec (CHUM, CHUQ, CHUSJ or MUHC).
- Patient suspected for a rare genetic disease after evaluation by a Medical Geneticist.
- At least one of the patient's parents is available for blood sampling.

Exclusion criteria:

- A conventional genetic analysis (microarray, small gene panel, single-gene testing or an alternative test) is expected to provide diagnosis.
- Patient is admitted for a reason not expected to be linked to the suspected genetic disease.

THE HI/LO TRIAL

Hôpital de Montréal pour enfants
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McGill University Health Centre

THE Hi-Lo Trial

UNIVERSITY OF ALBERTA

Project Title: Does the Use of Higher Versus Lower Oxygen Concentration Improve Neurodevelopmental Outcomes at 18-24 Months in Very Low Birthweight Infants?

Type of study: Cluster crossover design unmasked randomized controlled trial (RCT)
Investigators: Dr. François Olivier (MUHC), Dr. Marc Beltempo (MUHC) & External PIs
Clinical Research Coordinator: Daniela Villegas M. (email: daniela.villegas.martinez@muhc.mcgill.ca)

Background: Oxygen is a vital element in the care of preterm infants and has been given more often than any other drug over the past 80 years. Despite this, we know very little about how much or how little oxygen is safe for preterm infants, particularly at birth. The minutes following birth are unique in that it is the only time during life when it is normal to have oxygen saturation (SpO2) values as low as 30%, which then increases over the next 7-10 min to values of 85%-95%. The use of supplementary oxygen may be crucial, but also potentially detrimental to premature infants at birth. High oxygen levels may lead to organ damage through oxidative stress, while low oxygen levels may lead to increased mortality.

Aim of the study: To determine if initiating resuscitation with a higher oxygen concentration of 60% compared to that of lower concentration of 30% increase or decrease the incidence of mortality or the presence of a major neurodevelopmental outcome between 18 and 24 months corrected age. Major neurodevelopmental outcome include any one of: (i) non-ambulatory cerebral palsy; (ii) severe cognitive delay, (iii) hearing impairment, and (iv) visual.

Summary of intervention: The initial steps of resuscitation will be carried out as per standard of care established by randomization at the time of your baby's birth, using an initial oxygen concentration of 30% or 60%. The oxygen concentration is then adjusted to reach the established targets of saturation for the first 10 minutes of life.

Inclusion criteria:

- Infants with gestational age between 23 0/7 to 28 6/7 weeks.
- Infants designated to receive full resuscitation.
- No known major congenital or chromosomal malformation.

Exclusion criteria:

- Infants born outside of study center.

More information:
https://www.hilotrial.org/

THE NEURO-NQI

Project Title: The NeuroNQI Pilot study: Effects of a Nurturing and Quiet Intervention (NeuroN-QI) on Preterm Infants' Neurodevelopment and Maternal Stress and Anxiety

Type of study: A Randomized Clinical Trial
Persons Responsible: Dr. Gabriel Altit (MUHC) and Dr. Marylin Aita (Sainte-Justine Hospital)
Clinical Research Coordinator: Charlotte Serrano (email: charlotte.serrano@muhc.mcgill.ca)

Background: The current state of knowledge reveals that the development of the brain of preterm babies is influenced by specific neonatal experiences during hospitalization, such as environmental sensory stimulation (light and noise), as well as proximity to mothers. However, there is a lack of evidence regarding the benefits that could be associated with the combination of care interventions to improve the health outcomes of preterm infants and their mothers, and in particular the development of the brain of infants during their hospitalization in the neonatal unit.

Aim of the study: To assess the feasibility and acceptability of a developmental care intervention including periods of nurturing between mothers and their infant (skin-to-skin contact/ Kangaroo care and auditory stimulation) to promote physical and emotional proximity and a quiet period (controlled light and noise levels and olfactory stimulation in incubators) and to estimate the effect of this intervention on infants' neurodevelopment as well as on maternal stress and anxiety.

Summary of intervention: Acquire light and noise measurements while kangaroo care is being done by the mother by using a photometer and a sonometer respectively.

Inclusion criteria:

- Infants born between 26 and 33 6/7 weeks.

Exclusion criteria:

- Birth defects or genetic disorders.
- An intraventricular hemorrhage >grade II.
- Receive analgesics or paralyzing agents.

Mothers exclusion criteria:

- <18 years of age, have a physical condition that does not allow kangaroo care, alcohol misuse, chose formula or mixed feeding; do not speak, read or write French or English.

More information:
https://www.neocardiolab.com/research-recherche/neuron-qi-project

THE PEACE STUDY

Project Title: Post-Extubation Assessment of Clinical stability in Extremely Preterm Infants (PEACE)

Type of study: Multiple center prospective observational study
Persons Responsible: Dr. Wissam Shalish, Dr. Guilherme Sant'Anna, Dr. Robert Kearney & External PIs

Clinical Research Coordinator: Ana Saavedra Ruiz (CUSM)
ana.saavedra.ruiz@muhc.mcgill.ca

Background: Almost all extremely preterm babies admitted to the NICU need a breathing tube connected to a ventilator to help them breathe after birth. The process of transitioning from invasive respiratory support (through a breathing tube) to non-invasive respiratory support (through a nasal mask or nasal prongs), also known as extubation, is a critical milestone in these babies. However, following extubation, these babies commonly have some form of clinical instability, including increased oxygen needs, increased work of breathing, and frequent cardiorespiratory events (where they have pauses in breathing, drops in their heart rate, and drops in their oxygen saturation). Also, a subset of these infants fail their extubation attempt and require re-insertion of the breathing tube, also known as reintubation. For these reasons, it is important to understand better why these fragile babies develop clinical instability and require reintubation.

Aim of the study: By collecting more detailed information about your baby's well-being, To evaluate the feasibility and acceptance of a multimodal monitoring system that integrates clinical data and biomedical signals during the post-intubation period in a cohort of extremely preterm infants.

Summary of intervention: Once the infant is deemed ready for extubation by the clinical team, clinical and physiological data (heart rate, breathing movement, oxygen saturation, brain and intestinal oxygenation) will be acquired continuously from 1-hour pre-extubation until 168 hours (7 days) post-extubation using different devices.

Inclusion criteria:

- Birth weight < 1000g and gestational age < 28+0 weeks.
- Received mechanical ventilation within the first 72h of life.
- Undergoing their first planned extubation within the first 6 weeks of life.

Exclusion criteria:

- Congenital anomalies and congenital heart disorders.

More information:
https://clinicaltrials.gov/study/NCT06037083

THE PURPOSE STUDY

Hôpital de Montréal pour enfants
Centre universitaire de santé McGill

Montreal Children's Hospital
McGill University Health Centre

Children's Hospital of Philadelphia

Project Title: : PurPOSE Study - Point of Care Ultrasound in Congenital Diaphragmatic Hernia: Predicting Outcomes and Success of Extubation

Type of study: Prospective observational study.
Persons Responsible: Dr. Gabriel Altit (MUHC) Other MUHC Collaborators, & External PIs
Clinical Research Coordinator: Daniela Villegas M. (email: daniela.villegas.martinez@muhc.mcgill.ca)

Background: Children with congenital diaphragmatic hernias are more likely to have been born with organs displaced in the chest leading to the need for certain surgical interventions or close monitoring. It is known that some of these children are born with heart and lung problems. We believe that chest ultrasound (with images from the lung and the heart), an imaging modality that is done without radiation, may already predict those babies that may have more complications or more problems before discharge from the hospital. Due to this hypothesis, we aim to assess if chest ultrasound on the first day of life and just before extubation may help better predict those that will have major issues as well as predict the successful extubation.

Aim of the study: To analyze chest ultrasound of the lung and the heart in order to better understand the impact of CDH after birth, and before extubation.

Summary of intervention: Ultrasound of the chest will be done on the first day of birth, as well as repeated in the hours prior to the planned extubation.

Inclusion criteria:

- Males and females less than 24 hours of life.
- Diagnosis of CDH (prenatally diagnosed).
- Gestational age ≥ 34 weeks.

Exclusion criteria:

- Prematurity (<34 weeks).
- Bilateral CDH.
- Postnatal diagnosis / outborn infants.
- Cyanotic congenital heart disease or complex non-cyanotic defects (excluding a patent ductus arteriosus (PDA), atrial septal defect (ASD) or ventricular septal defect (VSD)).
- Major congenital anomaly (such as brain or airway/lung malformation) or prenatally known genetic syndrome.
- Infants unable to recruit prior to cannulation on ECMO.

More information:
https://www.neocardiolab.com/research-recherche/ongoing-research-projects-projets-de-recherches-en-cours#h.vj39ehkxolkt

THE SANE-03
THE SILDENAFIL STUDY

Hôpital de Montréal pour enfants
Centre universitaire de santé McGill

Montreal Children's Hospital
McGill University Health Centre

Project Title: Treatment of Neonatal Encephalopathy with Oral Sildenafil Suspension to Repair Brain Injury Secondary to Birth Asphyxia: A Phase 2 study

Type of study: Randomized, double-blind, placebo-controlled clinical trial
Persons Responsible: Dr. Pia Wintermark
Clinical Research Coordinator: Joseph Zepeda (Email: joseph.zepeda@affiliate.mcgill.ca)

Background: The phase II study will be a double-blind, randomized placebo-controlled trial that will be started at the Montreal Children's Hospital and will be extended to other sites. Neonates will be randomized to receive either (1) sildenafil (experimental group) or (2) placebo (control group)twice a day for seven days (from day 2 of life to day 9 of life). The allocation ratio for the study will be 2:1, to allow for the assessment of the efficacy of sildenafil with a larger number of neonates. We will explore the change in the severity of brain injury determined by MRI between days 2, 10 and 30 of life. We will compare the MRI scores of brain injury severity on days 10 and 30 of life with baseline (day 2 of life) using the Wilcoxon signed-rank test. We will follow these babies at 18 and 36 months.

Aim of the study:
Primary Objective:
-Determine if sildenafil decreases brain injury

Secondary objectives:
-Further assesssafety ofsildenafil
-Determine if sildenafil improves cardiopulmonary hemodynamics
-Determine if sildenafil improves neurodevelopmental outcome
- Determine if sildenafil decreases neuroinflammation.

Summary of intervention: Neonates will be randomized to receive either sildenafil (experimental group)or placebo (control group) twice a day for seven days.

Inclusion criteria:
Male and female neonates meeting the criteria for induced hypothermia:

- Gestational age ≥ 36 weeks and birth weight ≥ 1800 g.
- Evidence of fetal distress, i.e., history of an acute perinatal event.
- Cord pH ≤ 7.0 or base deficit ≤ - 16 mEq/L.
- Evidence of neonatal distress, such as an Apgar score ≤ 5 at 10 minutes, postnatal blood gas pH obtained within the first hour of life ≤ 7.0 or base deficit ≤ - 16 mEq/L, or a continued need for ventilation initiated at birth and continued for at least 10 minutes.
- Evidence of moderate to severe neonatal encephalopathy by an abnormal neurological exam and/or an amplitude-integrated electroencephalogram (aEEG).
- They will receive whole-body cooling to an esophageal temperature of 33.5ºC, initiated within the first 6 hours of life, continued for 72 hours, and then they will be slowly rewarmed using standard protocol.
- Evidence of brain injury on a brain magnetic resonance imaging (MRI) performed on day 2 of life.

Exclusion criteria:

- Neonates with complex congenital heart disease.
- Neonates with cerebral malformations.
- Neonates with genetic syndrome.
- Neonates with intraventricular and/or intraparenchymal hemorrhage on MRI performed on day 2 of life.

More information:
http://www.neobrainlab.org

THE SPEC STUDY

Project Title: Surveillance of Postnatal steroids Effects on Cardiac Function and Lung Water Content in Extremely Preterm Infants with Evolving BPD: the SPEC study

Type of study: Multicentric prospective observational study
Persons Responsible: Dr. Gabriel Altit and Dr. Guilherme Sant'Anna (MUHC) and external PIs
Clinical Research Coordinator: Daniela Villegas M. (email: daniela.villegas.martinez@muhc.mcgill.ca)

Background: Currently, the use of postnatal steroids in preterm infants remains controversial mostly due to potential adverse effects on the neurological and cardiovascular systems. We recently reviewed our practice in infants born at less than 29 weeks of estimated gestational age and observed that the median cumulative dose of dexamethasone used was 1.19 mg/kg (IQR: 0.89 – 2.12), starting at the beginning of the third week of life. Thus, in practice we use a cumulative dose much lower than the one reported to be associated with LV hypertrophy. Nevertheless, anecdotally in a few cases, LV hypertrophy was noted with significant effects on heart structure and function shortly after the first doses of dexamethasone, indicating that there are other factors associated with cardiovascular side effects in these infants.

Aim of the study: to investigate the effects of dexamethasone on cardiac structure and/or performance and lung water content in the extremely preterm population undergoing treatment for significant lung disease.

Summary of intervention: Perform an echocardiogram, lung ultrasound and HRV (Heart rate variability at different time points of the DEXA treatment: Start, Day 3, Day 7, Day 14, then Day 7 post-treatment, Day 14 post-treatment and 36 weeks CGA.

Inclusion criteria:

- < 29 weeks of gestational age at birth admitted at the participating sites.
- To be initiated on dexamethasone therapy for treatment of significant lung disease as per medical team decision.

Exclusion criteria:

- Congenital heart disease (except: Atrial septum defect (ASD), Ventricular septum defect (VSD)). Major congenital anomalies/genetic disorder (Trisomy 13, 18, 21).
- Congenital severe lung or airway malformation (Trachea-esophageal fistula, congenital pulmonary airway malformation, congenital diaphragmatic hernia). Twin-twin transfusion syndrome.

More information:
https://www.neocardiolab.com/research-recherche/ongoing-research-projects-projets-de-recherches-en-cours#h.sz6e41vnphng

THE UNICORN STUDY

Hôpital de Montréal pour enfants
Centre universitaire de santé McGill

Montreal Children's Hospital
McGill University Health Centre

abcdresearch
ADVANCES IN BRAIN & CHILD DEVELOPMENT RESEARCH LABORATORY

Project Title: Understanding Infant Cerebral growth & Outcome Research in Neurodevelopment (The UNICORN study)

Type of study: Prospective observational study
Persons Responsible: Dr. Marie Brossard Racine, PhD
Other contact: Helin Polat (email: helin.polat@rimuhc.ca) & Camille Héguy (email: camille.heguy@mail.mcgill.ca)

Background: Thanks to improved health care, most babies born preterm or with a congenital heart defect (CHD) grow up to be independent adults and have satisfying lives. However, some may develop functional difficulties during childhood and adolescence. However, the relationship between these difficulties and brain development remains poorly understood. This information could help us identify sooner the children who will be facing challenges so we can react promptly. Overall, a better understanding of these will guide the development of targeted interventions and help us provide better support to babies and their families.

Aim of the study: This research study seeks to better understand brain growth and child development during the first 2 years.

Summary of intervention: Perform magnetic resonance imaging and/or age-appropriate neurodevelopmental evaluations following discharge (starting at term equivalent for the preterm born babies or post-open heart surgery for the babies with CHD) and every season (~3 months) during the first 12 corrected age. Also, perform age-appropriate evaluations only every 6 months during the second year of life.

Inclusion criteria:

Babies born preterm :

- Infants born ≤ 37 weeks gestational age at the Montreal Children's Hospital.

Babies with CHD:

- Infants with CHD who underwent open heart surgery utilizing cardio-pulmonary bypass during the first six months of life.

Exclusion criteria:

- Presenting with brain malformation or severe brain injury detected by bedside ultrasound
- Congenital infection, genetic syndrome, or documented chromosomal anomaly

More information:
https://www.abcdresearch.ca/projects

THE WHEAT INTERNATIONAL TRIAL

Hôpital de Montréal pour enfants
Centre universitaire de santé McGill

Montreal Children's Hospital
McGill University Health Centre

WHEAT

IWK Health

Project Title: WithHolding Enteral Feeds Around Packed Red Cell Transfusion (WHEAT)

Type of study: Randomized controlled, unblinded, multicentric trial.
Persons Responsible: Dr. Marc Beltempo (MUHC) & other external PIs
Clinical Research Coordinator: Daniela Villegas M. (email: daniela.villegas.martinez@muhc.mcgill.ca)

Background: Necrotizing enterocolitis is a serious complication related to prematurity. Almost 5% of infants born at <30 weeks gestation will develop necrotizing enterocolitis which can lead to death or long-term health and developmental problems among survivors. Red blood cell transfusion has been suggested as a possible factor that contributes to the risk of necrotizing enterocolitis. This transfusion-associated necrotizing enterocolitis may also be more severe with higher mortality. The majority of preterm infants born <30 weeks (60% to 90% have at least one transfusion) will require at least one transfusion during admission. Stopping milk feeds for a short period of time (12h) during red blood cell transfusion may reduce the risk of necrotizing enterocolitis by decreasing postprandial mesenteric. However, due to a lack of good-quality evidence, there is no consensus regarding the optimal feeding strategy during a blood transfusion.

Aim of the study: Compared with continuing feeds, withholding feeds during each packed red cell transfusion after randomization will reduce the incidence of NEC occurring after the first packed red cell transfusion.

Summary of intervention: Babies will be randomized before receiving a blood transfusion to stopping feeds during transfusions or continuing feeds during transfusions.

Inclusion criteria:

- Preterm birth at <30+0 weeks of gestational age.

Exclusion criteria:

- Packed red cell transfusion with concurrent enteral feeds prior to enrolment (*infants who have received a packed red cell transfusion while nil-by-mouth or minimal enteral nutrition (<15 ml/kg/days feeds) are eligible).
- Infants where enteral feeding is contraindicated in the first 7 days after birth [e.g. Major congenital abnormality of the GIT].
- Previous episode of NEC or SIP prior to first packed cell transfusion.

More information:
http://neoepoch.com/wheat-trial

THE WIRELESS NICU

Hôpital de Montréal pour enfants
Centre universitaire de santé McGill

Montreal Children's Hospital
McGill University Health Centre

projet hôpital intelligent

smart hospital project

Project Title: The Use of Wireless Sensors in Neonatal Intensive Care

Type of study: Single center prospective observational study
Persons Responsible: Dr. Wissam Shalish & Dr. Guilherme Sant'Anna and Dr Robert Kearney (Biomedical Eng.)
Clinical Research Coordinator: Alyssa Maximov (email: alyssa.maximov@muhc.mcgill.ca)

Background: Infants admitted in the Neonatal Intensive Care Unit are all subject to continuous monitoring of vital signs such as heart rate, respiration and oxygen saturation (SpO2). These vital signs are measured non-invasively by placing sensors, leads, or bands directly on the patient's skin and connecting them to monitors via wires. Nurses, physicians and other providers routinely use these continuous vital sign values to make clinical decisions about their patients in real time. Unfortunately, despite witnessing rapid technological advances in smart monitoring and wearable devices across various industries, the healthcare sector has traditionally lagged. This is particularly pertinent to critical care units such as the NICU, where several monitoring limitations still exist.

Aim of the study: To demonstrate the feasibility of continuous wireless monitoring in term and preterm infants with variable degrees of maturity and levels of acuity in a busy NICU. To develop automated reports of physiological health (or impending ill health) using continuously acquired physiological signals from the wireless wearable devices. Lastly, to evaluate the accuracy of accelerometry in monitoring respiration and help classifying apneas via measurements of chest and abdominal wall movements.

Summary of intervention: For (a) Phase 1a - monitoring for 8h per day for 4 consecutive days, (b) Phase 1b - monitoring between 2h to 8h per day for 2 to 4 consecutive days, and (c) Phase 2 - monitoring for 96h continuously.

Inclusion criteria:

- Healthy term infants in room air at enrollment
- Term infants with perinatal asphyxia undergoing therapeutic hypothermia at enrollment
- Healthy preterm infants in room air at enrollment
- Preterm infants on CPAP at enrollment
- Preterm infants on conventional mechanical ventilation at enrollment
- Preterm infants on high frequency ventilation at enrollment
- Preterm infants on nasal intermittent positive end expiratory pressure at enrollment
- Preterm infants on CPAP at enrollment.

Exclusion criteria:

- Congenital anomalies and surgical conditions (ex: gastroschisis, omphalocele, congenital diaphragmatic hernia), congenital heart disorders, congenital skin infections or known conditions with fragile skin (such as epidermolysis bullosa).

More information:
https://www.smarthospitalproject.com/wireless-project/wireless-nicu

https://clinicaltrials.gov/study/NCT04956354?term=wireless%20NICU&rank=1

RESEARCHERS

DR. FRANCOIS OLIVIER

DR. GABRIEL ALTIT

DR. GUILHERME SANT'ANNA

DR. MARIE BROSSARD-RACINE

DR. KATRYN PAQUETTE

DR. WISSAM SHALISH

DR. JARRED GARFINKLE

DR. PIA WINTERMARK

DR. MARC BELTEMPO

DR. JESSICA DUBY

DR. MICHELLE RYAN