**Effect of Retinopathy of Prematurity Screening on cerebral and somatic (splanchnic) regional oxygenation and cardiorespiratory stability in neonates**

**ROP-Ox**

**Study type**: Prospective observational single-centre study

**U1111-1213-1086**

**Objectives:**

The primary aim of this study is to determine the whether retinopathy of prematurity (ROP) screening in neonates adversely affects cerebral and gastrointestinal regional oxygenation at the time of instillation of eye drops and of eye examination.

The secondary aims of this study include whether:

1. Retinopathy of prematurity screening in neonates results in an adverse effect on markers of cardiorespiratory stability as measured by oxygen saturations and non-invasive blood pressure measurement
2. Retinopathy of prematurity screening results in adverse effects on abdominal blood flow velocities as measured by Doppler of the coeliac trunk and superior mesenteric artery.

**Inclusion and exclusion criteria:**

Infants will be considered for recruitment into the study if they meet the criteria for screening for ROP

**Study methods:**

This is an observational study. The decision to screen a neonate for retinopathy of prematurity is based on evidence-based local guidelines (see Appendix 1).

Informed parental consent will be obtained in all cases prior to data collection.

Once the parental consent is obtained, following data will be collected as part of this study:

Patient characteristics:

* Gestational age
* Postnatal age
* Ethnicity
* Sex
* Birth weight (customized centile)
* Weight at time of ROP screening
* Respiratory support required at time of examination
* Caffeine treatment

Cerebral and gastrointestinal near infra-red spectroscopy (NIRS)

Cerebral and gastrointestinal (splanchnic) oxygenation levels will be measured for 1hrs pre-, during and for 3 hours post ROP screening.

Multi-site NIRS system (Nonin SenSmartTM Model X-100) with non-adhesive regional oximetry sensors will be used (EQUANOX Advanced 9004CB-NA Paediatric/Neonatal). The Paediatric/Neonatal sensors have the advantage of having a completely flat surface to avoid pressure-related injury on fragile skin of infants. They will be attached to infants using soft elastic bandages or a Tegaderm, which are routinely used in clinical practice.

The sensors will be positioned using a standard template to minimise inter-observer variability in sensor placement. The following organ systems will be studied:

**Brain**: Left fronto-parietal area of infant’s head. Two lateral LED emitters should avoid the midline (to avoid interference by the sagittal sinus) and hair.

**Somatic (splanchnic bed):** Anterior abdominal wall in the midline 2cm below the umbilicus

Cardiorespiratory stability

1. Heart rate and peripheral arterial saturation will be recorded using a pulse oximeter for 1 hour prior to retinopathy screening, during instillation if eye drops, during ophthalmic examination and for 3 hours post examination.
2. Non-invasive, intermittent blood pressure monitoring will be performed using a neonatal blood pressure cuffs for prior to retinopathy screening, after instillation if eye drops, and after eye examination.
3. Ultrasound doppler will be used to measure abdominal blood flow velocities in the coeliac trunk.

Position of infants

Infants will be placed supine during data collection unless medically indicated for them to lie in other positions (sleep position of infants will be recorded as part of study). This is because sleep position is known to affect parameters of cardiorespiratory stability.

**Power analysis**: We calculated that a sample size of at least 30 infants is required to detect a significant increase of 10% in somatic regional oxygenation 24hrs post transfusion with 80% power using p-value of 0.05 and the margin of error of +/- 4%.

**Appendix 1: Wellington NICU Retinopathy of Prematurity Screening Protocol**

Eye checks are performed on

* All infants <1301 grams birth weight and all infants <31 weeks gestation at birth. [one criteria only needs to be met]
* Infants >1300 grams and >31 weeks will be referred for ROP screening only if the clinical course has been unstable and the infant is felt to be at high risk for ROP e.g. an infant who has required high Heart Rate and concentrations of oxygen

\*

Timing of the first examination

* Infants, 27 weeks at birth [i.e. up to 26+6] : first exam at 30-31 weeks post menstrual age
* Infants 27 weeks or beyond: first exam at 4-5 weeks [29-35 days ] post natal age

Follow up examination will be scheduled by the ophthalmologist based on findings at initial examination.

**Appendix 2: Study flow chart**

\*time may vary

BP

BP

BP

Start of Study

Eye Drops

Eye Exam

End of Study

NIRS

Heart Rate and PaO2

1 hr

1 hr\*

3 h

Coeliac

Doppler

Coeliac

Doppler

Coeliac

Doppler