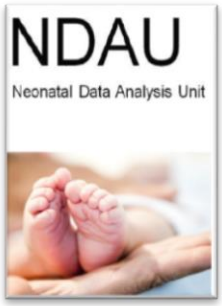
OPTI-SURF

Optimal surfactant delivery for preterm babies with respiratory distress syndrome



OPTI-SURF Study Team

c/o Dr Kevin Goss

Leeds Centre for Newborn Care
Leeds Children's Hospital
Leeds
LS1 3EX

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18th March 2018

Dear Dr

Re: OPTI-SURF: Optimising surfactant delivery for preterm babies with respiratory distress syndrome (CMPS ID: 36652; IRAS ID: 237111)

I am writing to introduce myself as the Chief Investigator for OPTI-SURF, a research project involving collaboration between Chiesi, Leeds Teaching Hospital NHS Trust, Imperial College and the Neonatal Data Analysis Unit (NDAU). OPTI-SURF is funded by Chiesi Limited, and supported by the NIHR CRN Portfolio, and is aimed to assess whether the dose and method of administration of surfactant given to preterm infants diagnosed with respiratory distress syndrome (RDS) affects neonatal outcomes.

In a research environment, the dose of surfactant is rigorously controlled, usually administered at a dose of 100mg/kg or 200mg/kg. In clinical practice, clinicians more frequently follow the 'whole vial dosing' approach, where a full vial is given aiming to get as close as possible to the desired dose. Reasons for whole vial use include reduction of waste and administration of surfactant shortly after birth where an infant's weight is unknown. It is unclear whether whole vial dosing leads to under-dosing or over-dosing and whether either situation affects outcomes.

The primary endpoint for this study is to investigate whether the first dose of surfactant (100-130 mg/kg compared to 170-200 mg/kg) has an effect on the requirement for mechanical ventilation within four days of birth in infants born at gestational age of 36^{+6} weeks^{+days} or less. Secondary objectives will include the association between first dose of surfactant with the requirement for re-dosing and respiratory outcomes (respiratory support at day 28 post birth, respiratory support at 36 weeks gestational age, duration of respiratory support, O_2 at discharge home and respiratory support at 2 years).

The drive towards minimally invasive treatments for premature infants as well as the potential difficulties associated with intubation for surfactant delivery has recently led to innovations in surfactant administration. Minimally (MIST) or less-invasive (LISA) surfactant administration techniques use a thin

catheter (Angiocath or nasogastric tube) to deliver surfactant whilst the infant is spontaneously breathing and this method is gaining popularity across Europe (although there remains little data on experience in the UK). A recent meta-analysis found that the use of LISA/MIST in preterm babies has reduced the composite outcome of death or bronchopulmonary dysplasia (BDP) at 36 weeks, the need for mechanical ventilation within 72 hours of birth, or need for mechanical ventilation anytime during the neonatal intensive care stay. Therefore a secondary aim of this study is to investigate the respiratory outcomes associated with the use of LISA/MIST in the UK.

It is proposed to minimise data collection requirements for this study through incorporation into routine clinical care. The data items required all form part of what would normally be recorded in a patient's case records. Hence it is proposed to obtain these from the Neonatal Network Research Database (NNRD). A small number of additional data items not currently held in the NNRD, are required for this study. They are, however, all items that would normally be recorded in the patient's case notes; hence it is proposed to incorporate these into the electronic data capture system, NNRD.

The results of the research will be made publicly available either in the form of a conference abstract/poster presentation, or submitted as a publication in a peer-reviewed journal within one year of study closure. The final data set will be available to other researchers via NDAU within three years of study end.

I am writing to seek agreement that data contributed by your unit to the NNRD may be included in this study. As this study uses data held in an existing research database, participation does not require approval from individual Trusts contributing data (Data Collection Centres) but only from the NHS Trust holding the database and Leeds Teaching Hospitals NHS Trust, which has been obtained. The study already holds United Kingdom Research Ethics Committee approval (attached) and Health Research Authority Approval (attached). Authorship of publications arising from this study will include "members of the UK Neonatal OPTI-SURF Collaborative".

If you would **not** like your neonatal unit's data to contribute to this project (i.e. you would like your unit to "opt-out") please inform ndau@imperial.ac.uk by 31st May 2018.

If you have any questions about this study please do not hesitate to contact me directly at kevingoss@nhs.net.

Yours Sincerely,

Dr Kevin Goss MB ChB PhD FRCPCH, Consultant Neonatologist, Leeds Teaching Hospitals NHS Trust

Collaborators: Prof N Modi and Dr C Gale, Imperial College London

Please note: By placing the attached parent information leaflet in your neonatal unit admission packs, current babies managed on your neonatal unit, up until 31st December 2019, will count as CRN accruals towards your NIHR portfolio targets.